



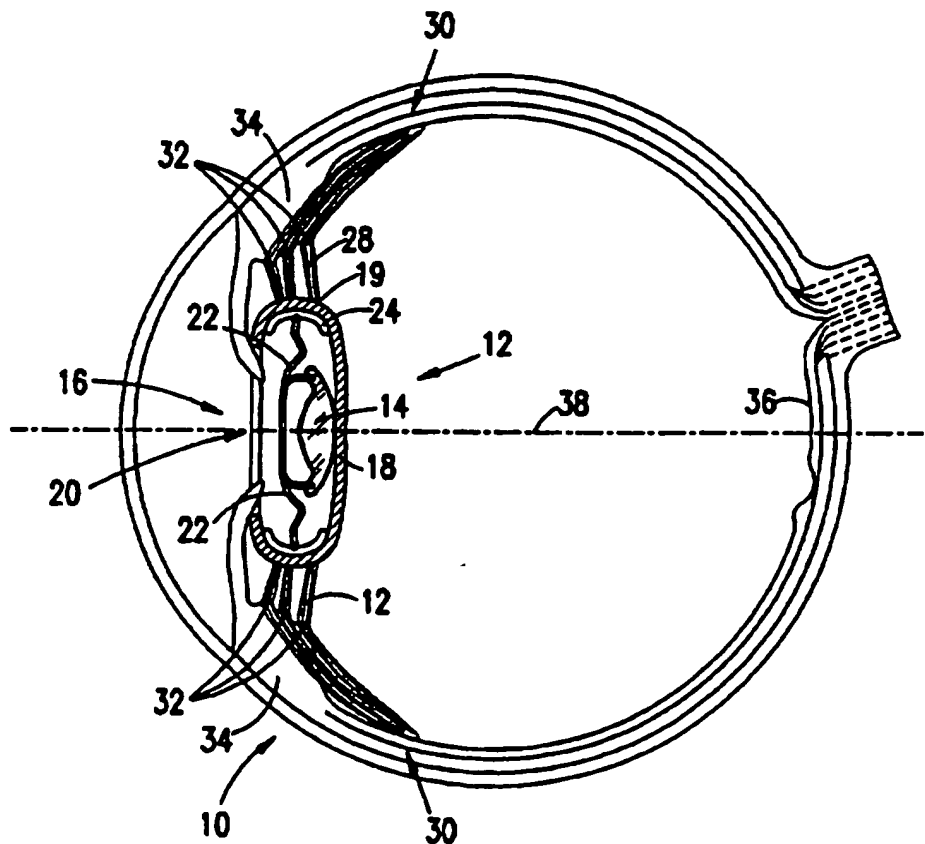
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(54) Title: ACCOMMODATING INTRAOCULAR LENS IMPLANT

(57) Abstract

An intraocular lens assembly for implantation in a human eye, said eye including a ciliary muscle and zonules controlled by the ciliary muscle, the assembly including: an optic having anterior and posterior surfaces depending from a common edge; at least two, preferably rigid, linkage arms, each being attached to the optic at a first position on the arm thereof and cooperating with ciliary muscle or the zonules at a second position on the arm; and at least two pivots, one of which is rotatably attached to each respective linkage arm intermediate the first and second positions.



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1 **ACCOMMODATING INTRAOCULAR LENS IMPLANT**2 **FIELD OF THE INVENTION**

3 This invention relates to an intraocular lens
4 assembly, for implantation into the human eye, which
5 permits accommodation in response to the contraction and
6 relaxation of the ciliary muscles.

7 **BACKGROUND OF THE INVENTION**

8 Normally when a person focuses on an object disposed
9 at a distance from the eye, focusing is achieved by virtue
10 of the contraction of the ciliary muscles which affects the
11 curvature of the lens and thereby its focal length. The
12 process whereby the eye is able to focus on objects over a
13 wide range of distances from the eye is called
14 "accommodation". It is known, during cataract operations,
15 for example, to remove material from the lens capsule and
16 replace it by an intraocular lens implant. The simplest of
17 such implants are fixed lenses having a single focal
18 length. Such lenses do not provide for any accommodation by
19 the eye for the distance of objects and therefore are of
20 relatively limited utility.

21 An improved type of lens for implantation provides a
22 number of focal lengths. Some of the light impinging the
23 lens is subjected to focusing at each of the different
24 focal lengths of the lens. This type of lens does provide
25 for a broader range of focus for the eye. Only a portion
26 of the light, however, is focused on the retina of the eye
27 for any of the focal lengths. Thus, if an object is focused
28 by one of the focal lengths, only 25-50% of the light will
29 be focused, the remainder will be only partly focused or
30 unfocused. This results in a reduction of contrast of the
31 focused object and a reduction in visual acuity.

32 A number of proposals have been made for changing the
33 focal length of the lens in response to the natural
34 accommodation mechanism of the eye. While these adaptive
35 lens proposals exist on paper, none of them are
36 commercially available and, as far as is known to the
37 applicant, none have been reported as having been
38 implemented in humans.

1 One type of adaptive lens comprises an artificial lens
2 whose shape is changed in response to the contraction and
3 expansion of the ciliary muscle. This type of lens is
4 proposed in US patents 4,842,601 to Smith, 4,888,012 to
5 Horn et al. and 4,253,199 to Banko.

6 Two other types of adaptive lenses are described in US
7 patent 4,994,082 to Richards et al. Some embodiments
8 described in this patent comprises one or two lenses whose
9 position in the plane perpendicular to optic axis of the
10 eye is adjusted by a mechanical structure effected by the
11 ciliary muscle of the eye. A second type of embodiment
12 utilizes two lenses (comprising a compound lens) whose
13 spacing along the optical axis is adjusted to change the
14 focal power of the compound lens. US patent 5,275,623 to
15 Sarfarazi show a similar type of compound adaptive lens.
16 U.S. Patent 4,892,543 to Turley describes a compound system
17 comprising a fixed lens having curved posterior and
18 anterior surfaces and a second component which is
19 positioned axially posterior of the lens. During
20 accommodation, the movable component is forced against the
21 posterior surface of the lens. The movement and subsequent
22 distortion of the movable portion results in a change in
23 the focal power of the compound lens.

24 U.S. patents 4,790,847 to Woods, 5,152,789 to Willis,
25 4,409,691 to Levy and 4,254,509 to Tennant describe
26 adaptive lens systems utilizing a simple intraocular lens.
27 These systems have focusing capabilities which are achieved
28 by axially shifting the lens in response to normal
29 contraction and expansion of the ciliary muscle resulting
30 from changes in range between the eye and an object under
31 observation. These patents (and the Turley and Richards et
32 al. patents) describe similar systems for providing motion
33 of the lens. In each case the ciliary muscle controls
34 zonules, which in turn provide tension to a lens capsule in
35 which the lens system is mounted. The extremities of the
36 capsule press against a radially compelled, spring-like
37 structure which also forms a relatively large angle of
38 somewhat less than 90° with the optical axis of the eye.

1 The lens is positioned on the optical axis. Relaxation of
2 the ciliary muscle releases the radial force and allows the
3 spring to form a more nearly flat shape. When the ciliary
4 muscle contracts, the pressure on the spring is increased
5 by the action of the lens capsule, the angle between the
6 spring and the optical axis is decreased, and the lens
7 moves axially away from the ciliary muscle. This causes an
8 increase of the offset of the lens from the plane of the
9 ciliary muscle. The movement of the lens changes the
10 position of the lens vis-a-vis the retina resulting in
11 accommodation of the eye for the distance of a viewed
12 object.

13 The bias of the lens with respect to the eye is
14 different for the various patents, with Tennant, Willis,
15 Turley and Levy having the lens biased toward the posterior
16 of the eye and Woods having the lens biased toward the
17 anterior of the eye.

18 The theory on which Woods bases his approach is that
19 of the classical Helmholtz hypothesis of accommodation, in
20 accordance with which when the eye is focused for far
21 vision, the ciliary muscle relaxes and the lens capsule
22 assumes a more discoid shape. This occurs because the
23 extremities of the lens capsule are attached via the
24 zonular fibers to the ciliary muscle. According to
25 Helmholtz, contraction of the ciliary muscle reduces
26 tension in the zonular fibers whilst relaxation of the
27 ciliary muscle has the reverse effect.

28 In the Woods patent the system includes an optic
29 (lens) and at least two rearwardly extending haptics which
30 bear against the circumference of the lens capsule and are
31 so formed that the lens bears against the anterior wall of
32 the lens cavity when the ciliary muscle is contracted, thus
33 adjusting for correct near vision.

34 Woods provides a very detailed resume of the relevant
35 prior art and, rather than describe the techniques which
36 have been used for intraocular implant, the reader is
37 referred to the Woods patent which is incorporated herein
38 by reference.

1 U.S. Patent No. 4,409,691 to Levy is also based on the
2 Helmholtz model but uses a different arrangement to provide
3 accommodation. In Levy, the optic is provided with a pair
4 of radially extending struts which are molded integrally
5 with the optic and are just long enough so that their
6 respective terminations are in light pressure contact with
7 the perimeter of the lens capsule when the optic is
8 implanted in the eye, the ciliary muscle then being
9 relaxed. The optic itself bears against the posterior
10 cavity wall and provides correct focus for far vision.

11 In Levy the capsule is controlled by the ciliary
12 muscle itself and not by the zonules, which may, in fact,
13 be removed and replaced by a soft cushion in one of his
14 embodiments. In accordance with the Helmholtz hypothesis,
15 the ciliary muscle contracts as the eye tries to focus on a
16 nearby object, it drives the outer end of the struts
17 radially inwardly, thereby forcing the optic forwardly,
18 away from the fovea centralis and increasing the optic-to-
19 image distance. This allows the eye to focus on relatively
20 near objects.

21 When the eye tries to focus again on far objects, the
22 ciliary muscle relaxes, the extremities of the lens capsule
23 move radially outward and the compressive force bearing on
24 the struts is reduced, allowing the optic to move further
25 back toward the posterior cavity wall.

26 Both Woods and Levy are based on the same principle,
27 namely the movement of the lens away from the fovea during
28 accommodation when the ciliary muscle contracts. In Woods,
29 the haptics are constructed such that the contraction of
30 the ciliary muscle causes the lens to be forced against the
31 anterior wall of the lens capsule while in Levy the struts
32 are so constructed that the lens is moved away from the
33 fovea by the posterior wall of the lens capsule.

34 Recent research, however, indicates that the Helmholtz
35 hypothesis of accommodation for near vision may be
36 incorrect. Specifically, Ronald A. Schachar reports in
37 Ann. Ophthal. 1992; 24:445-452 that, during accommodation,
38 contraction of the ciliary muscle results in an increase in

1 zonular tension. Thus, according to Schachar, "the
2 equatorial diameter of the lens is actually increased in
3 contrast to Helmholtz's hypothesis and its modifications.
4 When the ciliary muscle contracts during accommodation, the
5 peripheral volume of the lens is decreased, resulting in an
6 increase in the central volume of the lens and the optical
7 power of the lens". This conclusion is reiterated by
8 Schachar in Ann. Ophthal. 1993; 25:404-409 wherein he
9 states:

10 "Helmholtz's hypothesis of accommodation and its
11 modifications state that the equatorial diameter of the
12 lens decreases during accommodation. In contradiction,
13 Schachar's hypothesis asserts that the equatorial diameter
14 of the lens increases with accommodation."

15 Further research by Schachar, Ann. Ophthal. 1994;
16 26:4-9 corroborates his hypothesis.

17 Consequently, the theory in accordance with which the
18 Woods patent is based, namely the change in tension of the
19 zonules with accommodation, may be incorrect and the device
20 of Woods, if one were to install it in a patient, could
21 give reverse accommodation.

22 One problem which occurs with the implantation of
23 accommodating lenses having a fixed focal length relates to
24 the need to provide sufficient axial displacement of the
25 optic within the eye in order to provide correct focusing
26 throughout the complete range from near to far vision. It
27 will be understood that the ciliary muscles themselves
28 undergo a maximum radial displacement of approximately 200
29 micrometers from their relaxed to contracted conditions.
30 Additionally, for a fixed focal length optic, an axial
31 displacement of approximately 1 mm is necessary to allow
32 for complete accommodation. In other words, the very
33 slight radial displacement of the ciliary muscle must be
34 amplified in order to allow for complete accommodation.

35 Prior art patents attempt to achieve this
36 amplification of movement by providing haptics (or struts
37 or other coupling elements) which form a relatively large
38 angle with the optic axis. Thus, small radial movements of

1 the ciliary muscle are translated into much larger
2 movements in the direction of the optical axis. This
3 amplification is approximately equal to the tangent of the
4 angle with the optical axis. This amplification is
5 reduced, however, by inherent flexibility of the coupling
6 elements. Moreover, such amplification is very sensitive to
7 the angle of the elements with the optical axis, which
8 angle itself varies with the amount of accommodation and is
9 not well controlled.

10 Furthermore, no surgical adjustment is made in the
11 prior art references for locating the intraocular lens
12 implant at precisely the correct distance from the retina
13 to allow for correct far or near vision. Thus, both Woods
14 and Levy who design their optics for correct far vision,
15 merely assume that the ciliary muscle is relaxed (as
16 required by Helmholtz's hypothesis) and design the haptics
17 (or struts) and optic so that the optic is of proper
18 strength and is properly positioned to achieve focus for
19 distant objects when the eye is relaxed.

20 However, it would clearly be desirable to provide an
21 intraocular lens implant allowing for complete
22 accommodation and also permitting surgical adjustment so
23 that the eye is correctly focused without the need for
24 correction spectacles.

25 U.S. Patent 4,575,373 to Johnson describes a non-
26 accommodating (i.e., non-adaptive) lens whose shape may be
27 adjusted using an external laser which selectively heats a
28 portion of the periphery of the lens and causes the shape
29 of the lens to change. This causes a permanent change in
30 the focal power of the implanted lens. However, there is no
31 teaching of how such an adjustable lens may also be made
32 adaptive.

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SUMMARY OF THE INVENTION

1
2 The present invention provides an improved method and
3 apparatus for providing accommodation utilizing one or more
4 optics which move in response to changes in the ciliary
5 muscle and the zonules.

6 These improved methods are generally characterized by
7 improved control over the motion of the optic and/or
8 increased axial movement of the optic for a given change in
9 the tension in the ciliary muscle and the zonules.

10 In some embodiments of the invention this improvement
11 is achieved by utilizing rigid haptics or linkage arms
12 rather than resilient haptics. In other embodiments of the
13 invention this improvement is achieved by utilizing a
14 fulcrum and pivot structure for the haptics which act as
15 lever arms or linkages. Some embodiments of the invention
16 include both these improvements.

17 Within the context of the invention the terms
18 "rigid" and "flexible" or "resilient" have a special
19 meaning. The haptics attached to the optic in prior art,
20 such as in the Woods patent, to which reference has been
21 made, are, in fact, resilient wires formed of plastics or
22 any other biologically inert material. They are
23 sufficiently stiff so that when a compressive force is
24 applied thereto, they distort but do not buckle. Rather,
25 they push the optic to which they are attached forward
26 along the optical axis. However, they are also
27 sufficiently resilient so that when the compressive force
28 is reduced, they spring back under their own elasticity so
29 as to return the optic toward its original position. It is
30 this property, namely that a compressive force applied to
31 the lever arms does not cause them to buckle or otherwise
32 collapse, which is essential for prior art inventions, and
33 it is to this extent that the term "flexible, resilient" is
34 to be understood herein.

35 Many preferred embodiments of the present invention,
36 however, use substantially rigid elements, and in
37 particular substantially rigid linkage arms or haptics.
38 These elements are considered to be rigid because, in these

1 embodiments, they do not deform significantly under the
2 compressive or tensile forces present during accommodation.
3 They are, therefore, capable of transmitting forces applied
4 to them more efficiently than flexible elements and
5 potentially with greater mechanical advantage. It is in
6 this context that the term "rigid" is to be understood in
7 relation to the present invention. It should be
8 understood, however, that these "rigid" segments are made
9 of very thin material and may not be rigid under other
10 circumstances, such as during surgical implantation, when
11 greater force is applied to them so that they can be
12 inserted into the lens capsule.

13 Other preferred embodiments of the present invention,
14 however, may use linkage arms or haptics made of flexible,
15 resilient material, which may be similar to the haptic
16 materials used in Woods and other prior art patents.
17 Preferred embodiments of the present invention using
18 flexible, resilient linkage arms still differ from the
19 prior art, however, by virtue of their use of pivot
20 connections to convert radial motion of the ciliary muscle
21 and zonules to axial motion of the optic more efficiently
22 and with greater mechanical advantage.

23 The present invention also provides, in some
24 embodiments thereof for improved haptic configurations,
25 improved methods of attachment of haptics to the optic and
26 for improved methods of providing structure to the lens
27 capsule remaining after surgery to further increase the
28 effectiveness of the accommodation of the eye after lens
29 replacement.

30 In yet another aspect of the invention, method and
31 apparatus are provided for adjusting the position of the
32 optic during or after its implantation so as to provide
33 optimum accommodation.

34 Furthermore, embodiments of the present invention can
35 be designed to operate properly in the eye regardless of
36 whether the classical Helmholtz theory or the new Schachar
37 theory of accommodation is correct.

38 In one group of embodiments of the present invention,

1 an intraocular lens assembly incorporates an optic for
2 implantation within the lens capsule of the eye, the optic
3 being held in place by at least two substantially rigid
4 linkage arms, or haptics, which are attached at their inner
5 ends to the edge or face of the optic. The outer ends of
6 the linkage arms are coupled with the movement of the
7 zonules and the ciliary muscle. The optic, linkage arms
8 and connecting parts are made of biologically inert plastic
9 or other biologically inert materials.

10 In this group of embodiments, the linkage arms are
11 connected to pivot joints at one or both the inner and
12 outer ends thereof, which permit the arms to rotate about
13 the pivot axes in response to radial expansion or
14 contraction of the equatorial diameter of the capsule.
15 When the ciliary muscle of the eye is relaxed, for distance
16 vision, the arms hold the optic in a position which focuses
17 distant images onto the retina. When the ciliary muscle
18 contracts to accommodate for near vision, the equatorial
19 diameter of the lens capsule changes, exerting force on the
20 outer ends of the linkage arms and thereby causing them to
21 rotate about their pivots and shift the optic forward, away
22 from the retina, so as to focus near images onto the
23 retina. When the ciliary muscle again relaxes, the linkage
24 arms move in the opposite direction, returning the optic to
25 its previous position of distant focus.

26 It may be appreciated that the equatorial diameter of
27 the lens capsule is determined at any time by the balance
28 of outward radial force exerted by the zonular fibers and
29 inward force due to the natural elasticity of the lens
30 capsule. Furthermore, the portions of the lens capsule
31 remaining after surgery, particularly the posterior wall of
32 the lens capsule, provide, in some embodiments of the
33 invention, a force which (axially) biases the optic toward
34 the front of the eye. Further embodiments of the invention
35 provide other elements for exerting forces which may affect
36 the balance of forces acting on the optic and change its
37 axial position.

38 In some preferred embodiments of the present

1 invention, the outer ends of the linkage arms are held in
2 contact with or attached to an expanding ring, which is
3 itself in contact with the edges of the lens capsule
4 adjacent to the zonules. The expanding ring serves both to
5 hold the capsule open (i.e., to prevent is axial collapse)
6 and to couple the linkage arms to the motion of the
7 zonules. This expanding ring may also exert an additional
8 outward radial force on the equatorial edge of the capsule
9 or may be segmented so that it provides only to position
10 the linkage arms and to hold the lens capsule open.

11 Further embodiments of the invention incorporate two
12 or more springs or other tensile members attached at one of
13 their respective ends to the ciliary muscle, zonules or
14 expanding ring at symmetrically spaced points surrounding
15 the capsule of the eye. The other ends of the springs are
16 either fastened together centrally or attached to the
17 ciliary muscle, zonules or expanding ring in such a way as
18 to cause an inward radial force to be exerted on the
19 equatorial edge of the capsule. For example, such tensile
20 members may take the form of a tensioned ring attached
21 along the periphery of the lens capsule. This type of
22 tensile member effectively reinforces the inherent tension
23 of the edge of the lens capsule itself. Such tensioned
24 members are especially useful when the posterior wall of
25 the lens capsule is also removed.

26 The ciliary muscle or zonules produce a contrary
27 force, in the outward axial direction. Outward radial
28 motion of the zonules or ciliary muscle will stretch the
29 springs, increasing the forward axial force and causing the
30 optic to move forward in the capsule. When the zonules or
31 ciliary muscle subsequently return radially inward, the
32 linkage arms will force the optic back to its previous
33 position.

34 In general, the lens capsule itself performs a similar
35 function, in a somewhat different way. The elasticity of
36 the capsule, especially when the capsule is held open by
37 the expanding ring, exerts an inward force on the edge of
38 the lens capsule, where it is attached to the zonules. The

1 posterior wall of the lens capsule performs an additional
2 function in many embodiment of the invention, in that in
3 these embodiments the optic is in contact with the
4 posterior wall of the lens capsule. Under this condition,
5 the posterior wall acts on the optic to provide a restoring
6 force for the optic when the diameter of the lens capsule
7 increases. In this way it is not necessary to attach the
8 outer edge of the haptics to the expanding ring to provide
9 movement of the optic when the diameter of the lens capsule
10 is increased.

11 In a preferred embodiment of the invention, in
12 accordance with Schachar's theory of accommodation, the
13 optic is positioned initially, for distant vision, in
14 contact with the posterior wall of the capsule of the eye.
15 Two or more linkage arms, made of rigid plastic or other
16 rigid material, are coupled flexibly to the optic so as to
17 permit the linkage arms to pivot at the coupling during
18 motion of the linkage arm, while still transmitting full
19 axial motion from the arm to the optic. The outer ends of
20 the linkage arms are likewise preferably flexibly attached
21 to an expanding ring, which holds them in place at the edge
22 of the capsule adjacent to the zonules.

23 According to Schachar's theory, when the eye
24 accommodates for near vision, contraction of the zonules
25 exerts an outward radial force, which causes the equatorial
26 diameter of the lens capsule to increase. Consequent
27 expansion of the expanding ring causes the arms to rotate
28 in their respective pivot joints on the expanding ring and
29 on the optic, thereby causing the optic to move axially
30 forward in the capsule. The linkage arms are geometrically
31 constructed in such a way that a small change in the
32 equatorial diameter of the capsule will cause a larger
33 change in optic position, sufficient to provide for focus
34 of near images onto the retina.

35 An alternative preferred embodiment of the invention
36 is similar to the embodiment described above, but is
37 designed to operate in accordance with Helmholtz's theory.
38 In this alternate embodiment the optic is coupled to the

1 expanding ring by two or more linkage mechanisms, each of
2 which comprises an inner arm and an outer arm. The inner
3 arm is preferably rigidly connected at its inner end to the
4 optic, and by a pivot at its outer end to the inner end of
5 the outer arm. The outer arm is connected at its outer end
6 to the expanding ring. When the ciliary muscle contracts
7 for near vision accommodation, according the Helmholtz, the
8 elasticity of the lens capsule causes the capsule's
9 equatorial diameter to decrease and forces the expanding
10 ring to contract. This contraction causes the outer arms
11 to rotate about their pivots in such a way that the angle
12 between the inner and outer arms at the pivot connecting
13 them decreases. The inner and outer arms are so arranged
14 that this rotation and decrease in pivot angle will cause
15 the optic to move axially forward, thus providing for near
16 images to be focused onto the retina.

17 The use of rigid linkage arms or haptics
18 differentiates the above preferred embodiments and other
19 alternative embodiments of this invention from prior art
20 patents cited above, such as Woods and Levy. The
21 aforementioned patents employ deformation of flexible wire
22 haptics to convert radial motion of the ciliary muscle and
23 zonules to axial motion of the optic. Some preferred
24 embodiments of the present invention include rigid
25 linkages, which do not substantially deform under the
26 forces exerted by the ciliary muscle, zonules and lens
27 capsule, and therefore transmit motion to the optic in a
28 more efficient and reliable way.

29 Other preferred embodiments of the present invention,
30 however, may use linkage arms or haptics made of flexible,
31 resilient material, which may be similar to the haptic
32 materials used in Woods and other prior art patents or may
33 alternatively use rigid materials. The resilient materials
34 are sufficiently stiff so that when a compressive force is
35 applied thereto, they do not buckle, and when the
36 compressive force is reduced, they spring back under their
37 own elasticity to their previous shape. Preferred
38 embodiments of the present invention using flexible,

1 resilient linkage arms still differ from the prior art,
2 however, by virtue of their use of pivot connections to
3 convert radial motion of the ciliary muscle and zonules to
4 axial motion of the optic more efficiently and with greater
5 mechanical advantage.

6 In accordance with other preferred embodiments of the
7 present invention, flexible, resilient linkage arms may be
8 radially pre-loaded, for example by the pressure of the
9 posterior wall of the lens capsule on the optic, so as to
10 hold the intra-optic assembly in place without their
11 connection to an expanding ring.

12 In other preferred embodiments of the invention, the
13 outer ends of the linkage arms, whether rigid or flexible,
14 may be fastened directly or indirectly to the zonules,
15 ciliary muscle or radial edge of the lens capsule by
16 suturing or gluing. It may be appreciated that the various
17 types of mechanical linkages described here in relation to
18 the various preferred embodiments of the invention may be
19 used alternatively in conjunction with an expanding ring or
20 with other methods, described herein, of coupling the
21 linkage arms to the motion of the zonules or ciliary
22 muscle.

23 In some preferred embodiments of the invention, the
24 linkage arms or haptics are constructed of either rigid or
25 resilient material, and are coupled to the edge of the
26 capsule adjacent to the zonules, preferably by an expanding
27 ring. A substantially rigid ring is connected by a pivot
28 to each of the linkage arms at a point between the arm's
29 outer end and its inner pivot connection to the optic. The
30 substantially rigid ring has a diameter smaller than the
31 minimum equatorial diameter of the capsule, but larger than
32 the optic and generally coaxial to it. The pivots on the
33 rigid ring serve as fulcrums, and the linkage arms act as
34 levers, rotating about the fulcrums when the capsule's
35 equatorial diameter changes. In accordance with Schachar's
36 theory, the linkage arms may be constructed so that when
37 the equatorial diameter of the capsule increases, said
38 lever action will cause the optic to move forward.

1 An alternative embodiment of the invention, in
2 accordance with Helmholtz's theory, similarly includes
3 rigid or resilient linkage arms, connected to a rigid ring
4 with pivots acting as fulcrums for lever action of the
5 arms, as in the preceding embodiment. In this alternative
6 embodiment, however, the linkage arms are constructed so
7 that when the equatorial diameter of the capsule decreases,
8 said lever action will cause the optic to move forward.

9 In a further preferred embodiment of the invention,
10 two optics are used, one of which is adjacent to the
11 posterior wall of the lens capsule and the other is held
12 parallel and anterior to it, with an intervening space
13 between them. The refractive power of the optics and the
14 spacing between them is so designed that when the ciliary
15 muscle is relaxed, distant objects are focused onto the
16 retina. Each optic is held in place by two or more linkage
17 arms or haptics, which are shaped and positioned in such a
18 way as to cause each of the arms of the anterior optic to
19 come into contact with and cross a corresponding arm of the
20 posterior optic, at a pivot point along or near the
21 equatorial plane of the capsule.

22 These points of contact of the corresponding anterior
23 and posterior linkage arms are located at a radius from the
24 center of the capsule that is greater than the radii of the
25 two optics but smaller than the total equatorial radius.
26 The outer ends of the arms are flexibly anchored to an
27 expanding ring at the edge of the lens capsule, adjacent to
28 the zonules. When the ciliary muscle contracts and the
29 equatorial diameter of the capsule decreases, in accordance
30 with Helmholtz's theory, the angle of crossing between the
31 corresponding anterior and posterior linkage arms increases
32 in a scissors-like action, which in turn increases the
33 spacing distance between the anterior and posterior optics.
34 As this spacing increases, the laws of optics provide that
35 the refractive power of the lens couple will decrease,
36 thereby allowing near objects to be focused onto the
37 retina. The illustrated embodiment operates according to
38 the Helmholtz theory. Similar embodiments, utilizing the

1 same principles can be applied to design of lens couples
2 which operate according to the Schachar theory.

3 One aspect of the present invention also provides
4 means and method for the surgeon to adjust the focusing
5 mechanism during or after implantation, so as to optimize
6 the near and distant focus of the intraocular lens
7 assembly. While the large range of optic motion afforded
8 by the invention may allow the patient to achieve full near
9 and distant accommodation without the need for adjustment,
10 surgical adjustment of the focal position may improve post-
11 operative vision in cases where this full motion cannot be
12 achieved.

13 For this purpose, alternative preferred embodiments of
14 the invention provide for either a rigid ring, coaxial with
15 and surrounding the optic, or the linkage arms, or both of
16 these structures, to be formed with a plurality of kinks.
17 A tool is provided for the purpose of straightening the
18 kinks in the ring in a controlled and graduated manner, so
19 as to increase the diameter of the ring, causing the optic
20 to move away from the capsule wall and closer to the
21 equatorial plane of the capsule. A further tool is
22 provided for straightening the kinks in the linkage arms,
23 thereby moving the pivot fulcrum points of the linkage arms
24 away from the optic and pushing the optic farther back in
25 the capsule. The surgeon may thus adjust the position of
26 the optic when the ciliary muscle is relaxed, so as to
27 achieve the best focus of distant objects on the retina.
28 When the ciliary muscle contracts, the entire range of
29 motion of the edge of the capsule adjacent to the zonules
30 will be utilized to achieve accommodative motion of the
31 optic within the capsule.

32 There is therefore provided, in accordance with a
33 preferred embodiment of the invention an intraocular lens
34 assembly for implantation in a human eye, said eye
35 including a ciliary muscle and zonules controlled by the
36 ciliary muscle, the assembly comprising:

37 an optic having anterior and posterior surfaces
38 depending from a common edge;

1 at least two linkage arms, each being attached to the
2 optic at a first position on the arm thereof and
3 cooperating with ciliary muscle or the zonules at a second
4 position on the arm; and

5 at least two pivots, one of which is rotatably
6 attached to each respective linkage arm intermediate the
7 first and second positions.

8 There is further provided, in accordance with a
9 preferred embodiment of the invention, an intraocular lens
10 assembly for implantation in a human eye, said eye
11 including a ciliary muscle and zonules controlled by the
12 ciliary muscle, the assembly comprising:

13 an optic having anterior and posterior surfaces
14 depending from a common edge; and

15 at least two substantially rigid linkage arms, each
16 being attached to the optic at a first position on the arm
17 thereof and cooperating with ciliary muscle or the zonules
18 at a second position on the arm.

19 There is further provided, in accordance with a
20 preferred embodiment of the invention, for use with the
21 intraocular lens assembly according to the above preferred
22 embodiments in which kinks are provided in said linkage
23 arms or in an optional rigid ring, an adjustment tool for
24 removing said kinks, the adjustment tool comprising:

25 a pincer having a pair of handles and two pairs of
26 aligned jaws opposite said handles rotatable about a hinge
27 axis, for insertion into the ciliary body and supporting
28 thereon respective ones of said kinks, such that closing
29 the handle presses the kinks between respective pairs of
30 said jaws thereby flattening the kinks.

31 There is further provided, in accordance with a
32 preferred embodiment of the invention, for use with the
33 intraocular lens assembly according to the above preferred
34 embodiments in which kinks are provided in said linkage
35 arms or in an optional rigid ring, an adjustment tool for
36 removing said kinks, the adjustment tool comprising:

37 a pincer having a pair of handles and a pair of
38 substantially planar support members opposite said handles

1 rotatable about a hinge axis, for insertion into the
2 ciliary body and supporting thereon respective ones of said
3 kinks, and

4 a pair of flattening members cooperating with the
5 support members for pressing the kinks towards the support
6 members and thereby flattening the kinks.

7 There is further provided, in accordance with a
8 preferred embodiment of the invention, an intraocular lens
9 assembly for implantation in a human eye, said eye
10 including a ciliary muscle and zonules controlled by the
11 ciliary muscle and at least a portion of a lens capsule
12 including an edge thereof and at least a portion of a
13 posterior wall thereof, the assembly comprising:

14 an expanding ring associated with the edge which
15 contacts the edge portion of the lens capsule and
16 preferably the posterior wall and positions the posterior
17 wall toward the back of the eye from center of the lens
18 capsule; and

19 an optic associated with the expanding ring.

20 There is further provided, in accordance with a
21 preferred embodiment of the invention, an intraocular lens
22 assembly for implantation in a human eye, said eye
23 including a ciliary muscle and zonules controlled by the
24 ciliary muscle and at least a portion of a lens capsule
25 including an edge thereof, the assembly comprising:

26 an expanding ring associated with the edge portion of
27 the lens capsule and which provides a resilient radial
28 force on the edge; and

29 an optic associated with the expanding ring.

30 Preferably, the expanding ring bears against the edge
31 of the lens capsule and provides an outward radial force or
32 is attached to the edge and provides an inward radial
33 force.

34 There is further provided, in accordance with a
35 preferred embodiment of the invention, an intraocular lens
36 assembly for implantation in a human eye, said eye
37 including a ciliary muscle and zonules controlled by the
38 ciliary muscle and at least a portion of a lens capsule

1 including an edge thereof and at least a portion of a
2 posterior wall thereof, the assembly comprising:

3 an expanding ring associated with the edge comprising
4 alternating rigid and elastic portions; and

5 an optic associated with the expanding ring.

6 BRIEF DESCRIPTION OF THE DRAWINGS

7 In order to better understand the invention and to see
8 how it may be carried out in practice, some preferred
9 embodiments will now be described, by way of non-limiting
10 example only, with reference to the accompanying drawings,
11 in which:

12 Fig. 1 shows a cross-sectional view of an eye having
13 therein a lens capsule containing an intraocular lens
14 assembly according to a preferred embodiment of the
15 invention;

16 Figs. 2A and 2B are front and side views of a
17 preferred embodiment of the optic shown in Fig. 1;

18 Fig. 3 is a front cross-sectional view of a preferred
19 embodiment of the expanding ring shown in Fig. 1;

20 Fig. 4A and 4B are front and side, partially
21 sectioned, views of an alternative preferred embodiment of
22 the optic shown in Fig. 1;

23 Fig. 5 is a schematic representation of the
24 intraocular lens assembly according some aspects of the
25 present invention, useful for explaining the mechanical
26 operation thereof;

27 Figs. 6A and 6B are respective sectional elevations of
28 a preferred embodiment of the invention, which operates in
29 accordance with Schachar's theory of accommodation, showing
30 the relative displacement of the optic for far vision and
31 near vision, respectively;

32 Figs. 7A and 7B are respective sectional elevations of
33 a preferred embodiment of the invention, which operates in
34 accordance with Helmholtz's theory of accommodation,
35 showing the relative displacement of the optic for far
36 vision and near vision, respectively;

37 Figs. 8A and 8B are respective sectional elevations of
38 an alternative preferred embodiment of the invention, which

1 operates in accordance with Schachar's theory of
2 accommodation, showing the relative displacement of the
3 optic for far vision and near vision, respectively;

4 Fig. 9 is a front view of a preferred embodiment of
5 the optic shown in Figs. 8A and 8B;

6 Fig. 10 is an enlarged view of a preferred embodiment
7 of a pivot mechanism used in the embodiment of Fig. 9;

8 Figs. 11A and 11B are respective sectional elevations
9 of a preferred embodiment of the invention, which operates
10 in accordance with Helmholtz's theory of accommodation,
11 showing the relative displacement of the optic for far
12 vision and near vision, respectively;

13 Fig. 12 is a half-sectional elevation of a modified
14 intraocular lens assembly comprising two optics;

15 Fig. 13 is a front elevation of a modified, adjustable
16 optic having more than two fulcrums and associated levers;

17 Fig. 14 is a pictorial representation of a first
18 adjustment tool for use when implanting the intraocular
19 lens assembly according to the invention; and

20 Fig. 15 is a pictorial representation of a second
21 adjustment tool for use when implanting the intraocular
22 lens assembly according to the invention.

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1 DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

2 Fig. 1 shows a cross-section of a human eye 10 having
3 an adaptive intra-ocular lens system 12, in accordance with
4 a preferred embodiment of the invention, installed in place
5 of the original material in a lens capsule 16. In this and
6 all other cross-sectional diagrams of the eye and
7 structures therein, the cornea and other anterior portions
8 of the eye are at the left of the figure, and the retina
9 and posterior portions of the eye are to the right.
10 Intraocular lens system 12 comprises an optic 14 placed
11 within lens capsule 16. Lens capsule 16, from which the
12 original lens material has been removed, includes an outer
13 edge 19, which is left intact and, optionally, a posterior
14 wall 18 at least a portion of which may be left intact. At
15 least a portion of the original anterior wall of the
16 capsule is generally removed during the operation for
17 removal of the lens material leaving an opening 20, through
18 which the lens system is installed.

19 As shown more clearly in Figs. 2A, 2B, and 3, lens
20 system 20 also includes two or more linkage arms 22, also
21 known as haptics, which are attached to the optic 14 at one
22 end of the arms and which preferably rest on or are
23 pivotably attached to an expanding ring 24 at a second end
24 thereof. In a preferred embodiment of the invention shown
25 in Figs. 1-3, arms 22 are pivotably attached for limited
26 rotational motion at pivots 26, symmetrically placed on the
27 outer edge of the optic 14, and at pivots 27 on expanding
28 ring 24.

29 As shown in Fig. 1, one end of zonular fibers 28, also
30 known as zonules, is attached to edge 19 of lens capsule
31 16. The other end of the zonules is attached to the sclera
32 30 of the eye. Intermediate their ends, the zonular fibers
33 are acted upon by ligaments or the like 32 which are
34 controlled by ciliary muscle 34. The portion of the eye
35 comprising the ciliary muscle and the volume it encloses is
36 also known as the ciliary body.

37 Optic 14 produces an image on the retina at the back
38 of the eye 10 corresponding to a focal plane 36. In order

1 to provide accommodation, optic 14 is made capable of
2 movement along optical axis 38. As in the normal eye,
3 accommodation is made consequent to changes in tension of
4 the zonular fibers. This change in tension acts on optic
5 14 so as to alter the image distance from optic 14 to focal
6 plane 36.

7 In the preferred embodiment shown in Figs. 2A and 2B,
8 linkage arms 22 are made of a relatively rigid material and
9 are attached to the outer edge of optic 14 at pivot 26.
10 The pivot may be made of flexible material, which allows
11 twisting or rotation of the arms about the pivot in
12 response to rotational force applied to the arms 22, but
13 prevents substantial axial motion of the arms. This
14 flexible material may also be elastic, so that pivots 26
15 will exert a biasing force on arms 22, which will tend to
16 return optic 14 to its original position when the
17 rotational force applied to the arms is removed.
18 Alternatively, pivot 26 may be made of rigid material with
19 a bore through which arm 22 is inserted and fastened in
20 such a way that the arm may rotate about the axis of the
21 bore, but any substantial axial motion along the axis of
22 the bore is prevented.

23 Other constructions for the linkage arms 22 and for
24 their attachment to the optic may also be provided. In an
25 alternative preferred embodiment shown in Figs. 4a and 4b,
26 rigid linkage arms 22 are pivotably attached to the face of
27 optic 14. Pivots 26 may in this case be constructed in the
28 form of an indentation 21 in the face of optic 14, which is
29 filled with a flexible plastic material, and in which the
30 end of linkage arm 22 is embedded. In this manner, the
31 angle between linkage arm 22 and the optical axis 38 of
32 optic 14 may change in response to radial forces exerted on
33 the linkage arm, due to flexing of pivot 26. Alternatively
34 or additionally, portions of the haptics which are adjacent
35 to 26 are also made flexible.

36 Within the context of the invention the terms
37 "rigid" and "flexible" or "resilient" have a special
38 meaning. The haptics attached to the optic in prior art,

1 such as in the Woods patent, to which reference has been
2 made, are, in fact, resilient wires formed of plastics or
3 any other biologically inert material. They are
4 sufficiently stiff so that when a compressive force is
5 applied thereto, they distort but do not buckle. Rather,
6 they push the optic to which they are attached forward
7 along the optical axis. However, they are also
8 sufficiently resilient so that when the compressive force
9 is reduced, they spring back under their own elasticity so
10 as to return the optic toward its original position. It is
11 this property, namely that a compressive force applied to
12 the lever arms does not cause them to buckle or otherwise
13 collapse, which is essential for prior art inventions, and
14 it is to this extent that the term "flexible, resilient" is
15 to be understood herein.

16 Many preferred embodiments of the present invention,
17 however, use substantially rigid elements, and in
18 particular substantially rigid linkage arms or haptics.
19 These elements are considered to be rigid because, in these
20 embodiments, they do not deform significantly under the
21 compressive or tensile forces present during accommodation.
22 They are, therefore, capable of transmitting forces applied
23 to them more efficiently than flexible elements and
24 potentially with greater mechanical advantage. It is in
25 this context that the term "rigid" is to be understood in
26 relation to the present invention. It should be
27 understood, however, that these "rigid" segments are made
28 of very thin material and may not be rigid under other
29 circumstances, such as during surgical implantation, when
30 greater force is applied to them so that they can be
31 inserted into the lens capsule.

32 Expanding ring 24 is constructed so as to exert an
33 outward radial force, which will cause the ring to conform
34 to the edge 19 of lens capsule 16, and expand or contract
35 in response to expansion or contraction of the capsule,
36 respectively. Ring 24 serves to couple the outer end of
37 linkage arms 22 to edge 19, so that radial forces exerted
38 by zonules 28 and ciliary muscle 34 can act upon said arms.

1 Ring 24 may further serve to open capsule 16, i.e., to
2 separate the anterior and posterior portions of the lens
3 capsule, in place of the natural lens that was surgically
4 removed, so that the elasticity of the capsule may serve
5 more advantageously to exert inward radial force on the
6 lens assembly as described below.

7 In a preferred embodiment, shown in Fig. 3, ring 24
8 comprises alternating segments of rigid and compressible
9 materials. Rigid segments 25 ensure that ring 24 maintains
10 its circular shape and that the capsule does not collapse.
11 Compressible segments 29 exert tangential force on adjacent
12 rigid segments, causing the ring to expand if it is not
13 radially constrained. In the embodiment described here,
14 radial constraint is provided by edge 19 of the lens
15 capsule which is constrained from outward movement by the
16 resilient nature of the lens capsule.

17 In the preferred embodiment shown in Fig. 3, the ring
18 includes pivots 27, to which the outer ends of linkage arms
19 22 are attached. Such attachment may be made at the time
20 of manufacture of assembly 12, and pivots 27 may be similar
21 in construction to pivots 26 on the optic, as described
22 above. In an alternative embodiment, expanding ring 24 is
23 manufactured separately from optic 14 and linkage arms 22.
24 Expanding ring 24 may then be implanted in capsule 16 by
25 the surgeon. The surgeon may next position the optic and
26 insert the linkage arms into receptacles on the expanding
27 ring, such receptacles being produced in such a way as to
28 permit the ends of the linkage arms to be pressed or
29 snapped into them and held thereby, so that the linkage
30 arms may pivot about their axes while remaining permanently
31 fixed therein. Such a receptacle is shown for example in
32 Fig. 10.

33 In another alternative embodiment thereof, expanding
34 ring 24 may be provided without pivots. The outer ends of
35 linkage arms 22 bear against the inner surface of expanding
36 ring 24, but are not fastened thereto, and are thus free to
37 rotate about their own axes.

38 In a further alternative embodiment, expanding ring 24

1 may be eliminated, and linkage arms 22 may instead be
2 rotatably coupled at their outer ends to anchors, which may
3 be glued or sutured to capsule edge 19, zonules 28 or less
4 preferably, ciliary muscle 34. More preferably, the
5 expanding ring is not eliminated but is provided as a split
6 ring so that it exerts no force of its own in the radial
7 direction while preserving the lens capsule in an open
8 condition.

9 The preferred embodiments of the invention shown in
10 Figs. 1-4 and in Figs. 6 through 12 will generally be
11 described herein in terms of rigid linkage arms 22,
12 pivotably attached to expanding ring 24 and/or to a
13 relatively rigid ring. It will be appreciated, however,
14 that some embodiments of the invention may incorporate
15 either rigid or flexible, resilient linkage arms 22.
16 Furthermore, the linkage arms may generally be coupled to
17 optic 14 and to edge 19 of the capsule or zonules 28
18 according to any of the embodiments described herein.

19 Fig. 5 shows a schematic representation of the
20 intraocular lens assembly according some aspects of the
21 present invention, useful for explaining the mechanical
22 operation thereof and in particular in illustrating the
23 action of the forces that operate on intraocular lens
24 system 12, during accommodative motion of optic 14. The
25 embodiment of the present invention that is shown in Figs.
26 1-4 may be considered to be one preferred embodiment of the
27 more general scheme shown here in Fig. 5.

28 While Fig. 5 generally follows Schachar's theory of
29 accommodation, it should be understood that the principles
30 of the present inventions are equally applicable to the
31 Helmholtz theory of accommodation, as will be shown in some
32 of the examples described below.

33 In Fig. 5, the posterior wall 18 of the lens capsule
34 contacts the rear surface of optic 14. The resilience of
35 the posterior wall is indicated by springs to indicate that
36 the resilient wall biases the optic to the left, i.e., to
37 the front of the eye. An optional tensive element 96 may be
38 further provided between the ends 19 of the lens capsule as

1 described above. Additionally, the edge of the lens capsule
2 also acts as a tensile element 96. In addition the
3 expanding ring, not shown in Fig. 5, for simplicity, may be
4 present and may partially counteract the effect of the
5 posterior wall and tensile element 96.

6 One way of providing tensile elements 96 is to attach
7 an elastic ring, which is preferably in tension during both
8 far and near vision, to the zonules or to the edge of the
9 lens capsule. This attachment may be by suturing the
10 elastic ring to the edge of the lens capsule. Preferably,
11 when such tensile action is required, as for example, when
12 the posterior wall is removed, the expander ring is made
13 tensile, in use, rather than being in compression as
14 described above. Such a ring would be implanted by
15 expanding the ring utilizing a removable expanding ring,
16 suturing the ring to the edge of the lens capsule and then
17 removing the expansion ring. This type of tensile member
18 effectively reinforces the inherent tension of the edge of
19 the lens capsule itself.

20 The edge of the lens capsule is connected to springs
21 100 which represent the effect of the zonules.

22 At least two linkage arms 104 are connected to
23 opposing the edges of optic 14 where they are rotatable
24 about pivots 106. The corresponding outer positions on arms
25 104 bear against the ends 19 of the lens capsule. where
26 they pivot at pivot points 107. As described above, in
27 preferred embodiments of the invention an expanding ring 24
28 may intervene between arms 104 and zonules 100, although
29 arms 104 may also be secured to the zonules by gluing or
30 suturing. For the sake of simplicity, these elements are
31 not shown in Fig. 5. Furthermore, although arms 104 are
32 shown having substantially the form of the embodiment of
33 Figs 1-4, they may have the forms shown below in the other
34 embodiments of the invention, as appropriate.

35 The outward radial tension which is applied to lens
36 capsule edge 19 by zonules 100, which tension may be
37 considered to include, as well, outward radial force
38 exerted by expanding ring 24 in some preferred embodiments

1 of the invention.

2 In general, the axial position of the optic depends on
3 the balance of forces between the zonules 100 (and the
4 expanding ring, if present) which urge edge 19 of the lens
5 capsule outward and the resilience of the lens capsule (and
6 tensile element 96, if present) which urges the edge of the
7 lens capsule inward. The effect of the force of the
8 posterior wall 18 of the lens capsule on the optic also
9 tends to push edge 19 of the lens capsule, outward. In many
10 embodiments of the invention the urging of the optic by the
11 posterior wall enables the expanding ring 24 and the outer
12 end position on the linkage arms to be held in place
13 without any attachment of the lens assembly to the lens
14 capsule or to the zonules. This simplifies implantation
15 considerably.

16 In the arrangement shown in Fig. 5, increased outward
17 radial force on zonules 100, generally due to contraction
18 of the ciliary muscle, induces outward motion of edge 19.
19 This motion results in a net radial movement of the outer
20 ends of linkage arms 104, whereby tension in the posterior
21 wall (and tensile element 96, if present) is increased.
22 This will cause lens 14 to move forward (to the left),
23 until a new balance of forces is reached.

24 When the radial force on zonules 100 is reduced, edge
25 19 moves back inward, which would cause a reduction of the
26 tension in the posterior wall in the absence of optic 14.
27 However, this reduction in tension is at least partially
28 mitigated by pressure from the optic which is forced
29 against the posterior wall by the inward movement of the
30 outer edge of arms 104.

31 It may be appreciated that in preferred embodiments of
32 the present invention, a wide variety of mechanical designs
33 may be applied to the intraocular lens system and, more
34 specifically, to linkage arms 104 and pivots 106 and 107,
35 with the objective of increasing and otherwise controlling
36 the axial displacement of optic 14 resulting from radial
37 forces applied at pivots 107. Preferably, the ratio of
38 axial to radial displacement is large enough to provide at

1 least 5:1 amplification of the radial motion, so as to
2 provide substantially complete accommodation. In saying
3 this, it is understood that complete accommodation requires
4 an axial movement of the optic 14 of approximately 1 mm
5 whilst the maximum radial movement of the ciliary muscle 34
6 is approximately 200 micrometers. However, it will be
7 appreciated that other ratios may be employed as required.
8 In particular, a larger ratio will result in a range of
9 accommodation which is larger than required for near/far
10 vision. When such larger accommodation ratios are
11 available, the exact placement of the optic becomes less
12 critical since the contraction of the ciliary muscle will
13 be sufficient to provide full accommodation even if far
14 vision is overcompensated when the ciliary muscle is
15 relaxed.

16 Figs. 6A and 6B are partial cross-sections showing a
17 detail of a preferred embodiment of the intraocular lens
18 assembly 12 depicted in Fig. 1 and showing more clearly the
19 construction and operation of the linkage arm 22 and pivots
20 26 and 27. Linkage arms 22 are characterized by a radial
21 reach and axial reach. Radial reach is defined herein as
22 the sum of the respective radial distances of pivots 26 and
23 27 from the optical axis. Axial reach is defined as the
24 difference between the relative axial positions of these
25 pivots. Because the radial reach of linkage arm 22 is
26 greater than the axial reach, a small radial movement
27 applied to the outer end of arm 22 gives rise to a
28 correspondingly greater axial movement of the inner end to
29 which the optic 14 is attached.

30 In operation, in response to changes in the tension of
31 the zonular fibers 28, edge 19 of lens capsule 16, which is
32 adjacent to the fibers, moves radially in and out. This
33 radial movement causes force to be exerted on arms 22,
34 thereby causing the arms to rotate about pivots 26 and 27.
35 It will be appreciated that outward motion of the edge 19
36 of the lens capsule 16 will cause the outer end of arm 22,
37 which is attached to the expanding ring 24, to move
38 radially away from the optical axis 38, and the inner end

1 of arm 22 will then move axially forward, away from the
2 focal plane 36 of the eye.

3 In Fig. 6A, the zonular fibers 28 are at their maximal
4 extension, corresponding, in accordance with Schachar's
5 hypothesis, to accommodation of the eye for distant vision.
6 In this case optic 14 presses against the posterior wall 18
7 of the capsule, at such distance from focal plane 36 as to
8 create a focused image at the focal plane of objects
9 distant from the eye. In Fig. 6B, where accommodation of
10 the eye for near vision is shown, zonular fibers 28 have
11 contracted, pulling edge 19 of the capsule outwards, and
12 causing linkage arms 22 to rotate about pivots 26 and 27,
13 so that optic 14 moves to the left, away from the retina,
14 to such distance from the focal plane 36 as to create a
15 focused image at the focal plane of objects near the eye.
16 In the configuration shown in Figs. 6A and 6B, pressure of
17 posterior wall 18 of capsule 16 may exert a forward
18 resilient biasing force on optic 14 which moves the optic
19 to the left when the tension in the zonules increases, as
20 described above.

21 When the eye returns to distant vision accommodation,
22 zonular fibers 28 extend, causing outer edge 19 of the
23 capsule to contract due to inward radial force exerted by
24 the elastic capsule. As a result of this contraction,
25 linkage arms 22 will rotate back to the position shown in
26 Fig. 6A and will return optic 14 to its distant focus
27 position.

28 As noted above, in the preferred embodiment of the
29 invention described with reference to Figs. 6A and 6B, an
30 expanding ring 24 with pivots 27 is used to couple linkage
31 arms 22 to the edge of the capsule 19 and zonules 28, and
32 to exert an outward radial biasing force. Pivots 26 are
33 provided to connect arms 22 to the edges of optic 14.
34 Further as described above with respect to Fig. 5, capsule
35 wall 18 exerts an inward radial force on the edge 19 of the
36 capsule and a forward biasing force on the optic. We
37 note, however, that the mechanical principles operative in
38 the embodiment shown in Figs. 6A and 6B could more

1 generally be applied to alternative preferred embodiments
2 of the invention, utilizing other types of linkage arms,
3 pivots and couplings, as are described hereinabove. These
4 alternative elements could similarly be used in the
5 preferred embodiments of the invention to be described
6 below.

7 Figs. 7A and 7B show another preferred embodiment of
8 the invention that operates under the Helmholtz theory of
9 accommodation. In this case, it will be appreciated that
10 when the eye accommodates for near vision, zonular fibers
11 28 relax, causing edge 19 of the capsule to move inward.
12 In this embodiment, optic 14 is connected to expanding ring
13 24 by a pair of articulated linkages 50. Each linkage
14 comprises an outer arm 52 and an inner arm 54, connected
15 together by a pivot joint 56. Outer arm 52 is attached to
16 the expanding ring 24 by a pivot 48, which permits the
17 linkage to rotate in the plane of the cross section. Inner
18 arm 54 is fixed rigidly to optic 14 at point 51.

19 When the eye accommodates for distant vision, optic 14
20 rests against posterior wall 18 of the capsule at a
21 distance at which a focused image of distant objects is
22 formed on the retina. When the eye accommodates for near
23 vision, edge 19 of the capsule moves inward, causing pivot
24 48 to move radially inward and outer arm 52 to rotate
25 clockwise about pivot 48. Pivot 56 moves forward, to the
26 left as shown in Fig. 7B, causing optic 14 to be drawn
27 forward to a position farther from the retina, thus
28 allowing focused images of objects near the eye to be
29 formed on the retina. In this embodiment of the invention,
30 outer arm 52 must be pivotably attached to ring 24 which is
31 also preferably attached to or biased against edge 19 of
32 the lens capsule. In this way the motion of edge 19 is
33 reliably transmitted to outer arm 52.

34 In another preferred embodiment of the invention,
35 shown in Figs. 8A and 8B, and described herein in reference
36 to Schachar's theory of accommodation, the linkage arms may
37 be configured as levers, so as to further amplify the
38 radial motion of capsule edge 19. A rigid ring 55, whose

1 diameter is larger than that of the useful area of the
2 optic but smaller than the minimum equatorial diameter of
3 the lens capsule, is connected to the linkage arms by
4 pivots 57, and which are positioned to hold ring 55 coaxial
5 with optic 14.

6 Ring 55 is shown in front view in Fig. 9, together
7 with optic 14 and linkage arms 22. Fig. 10 shows a detail
8 of the construction of a preferred embodiment of linkage
9 arm 22, ring 55 and pivot 57 shown in Fig. 9. Ring 55 has
10 at least two sections 67 and 69, which are interconnected
11 by a biologically inert elastic sleeve 31 which fits over
12 the junction of the two sections 67 and 69 so as to leave a
13 small gap 33 therebetween which, owing to the elasticity of
14 the inert sleeve, allows twisting of the adjacent sections
15 67 and 69 of the pivot 57. The portion of the inert sleeve
16 33 intermediate the two sections 67 and 69 of the ring 22
17 is anchored to the linkage arm 22 so that, consequent to
18 application of radially directed force to the outer section
19 of the arm 22, the sleeve 33 twists, thereby allowing
20 rotation of the arm about pivot 57. By means of this
21 construction, the natural tendency of the biological tissue
22 to grow around the inert sleeve 33 owing to attempted
23 rejection by the body of the intraocular implant, which
24 constitutes foreign matter, does not impede the performance
25 of pivot 57.

26 The pivot embodiment described here in reference to
27 pivot 57 on ring 55, based on a flexible sleeve or other
28 flexible element coupling two rigid elements, may also be
29 useful in other pivots used in other preferred embodiments
30 of the invention, such as pivot 56, shown in Figs. 7A and
31 7B, and pivot 59 in Figs. 8A and 8B.

32 Referring again to Figs. 8A and 8B, it may be seen
33 that when zonules 28 draw the edge 19 of the capsule
34 radially outwards, as the eye accommodates for near vision,
35 arms 22 will act as levers, rotating about pivots 57, which
36 serve as fulcrums. Linkage arms 22 further pivot at pivot
37 connections 26 and 27, to the optic 14 and expanding ring
38 24 respectively, and flex at joint 59. Thus, the inner

1 portions 42 of the linkage arms 22, will pull the optic 14
2 axially forward. The mechanical advantage of the levers,
3 due to the inner lever arm 42 being substantially longer
4 than outer lever arm 40, will amplify small radial
5 movements of the edge of the lens capsule 28 into larger
6 axial movements of optic 14.

7 Figs. 11A and 11B show a cross-sectional view of
8 another preferred embodiment of the invention, operable
9 under the Helmholtz theory of accommodation. This
10 embodiment is similar to the preceding one, using linkage
11 arms 22 as levers, with pivots 57 on rigid ring 55 serving
12 as fulcrums. In the present embodiment, however, linkage
13 arms 22 are so configured that when accommodation of the
14 eye for near vision causes the edge 19 of the capsule to
15 move radially inward, linkage arm 22 will rotate about
16 pivot 57 in such a way as to cause optic 14 to move
17 axially to the left, away from the retina, as required for
18 near accommodation. Preferably, at least portions 59 and,
19 optionally, 61 of arm 22 are flexible to allow the arm to
20 rotate about pivot 57. Furthermore, pivot 26 is provided
21 between the arm and the optic as described above.

22 It may be appreciated that other preferred embodiments
23 of the present invention may use linkage arms 22 that are
24 formed of flexible, resilient material, as discussed
25 earlier, with or without expanding ring 24. Rigid ring 55
26 is still provided, with pivots 57 to act as fulcrums for
27 the lever action of arms 22. In these embodiments, the
28 resilient arms 22 are mechanically pre-loaded and hold the
29 optic 14 in place by pressure of their outer ends against
30 the edges 19 of the capsule. Such embodiments still
31 utilize the same mechanical leverage principles as the
32 preceding embodiments, which are based on rigid linkage
33 arms.

34 Fig. 12 shows, in cross-section, another embodiment of
35 the invention wherein a lens doublet comprising a pair of
36 optics 58 and 60 are employed, commonly connected by
37 respective linkage arms 62 and 64, commonly hinged to a
38 pivot 66 and anchored to a peripheral expanding ring 24

1 within the lens capsule 16. The various embodiments
2 described earlier with reference to the flexibility or
3 rigidity of the linkage arms, the methods of mounting them
4 to the optics and the methods of coupling them to the
5 motion of the zonules, also apply to the lens doublet shown
6 in Fig. 12. Optics 58 and 60 and the distance between them
7 are chosen so that when the zonules are relaxed, the
8 refractive power of the lens doublet is such as will cause
9 focused images of distant objects to be formed on the
10 retina.

11 In the arrangement shown in Fig. 12, following
12 Helmholtz's theory of accommodation, contraction of the
13 ciliary muscle results in an inwardly directed radial force
14 being applied to lever arms 62 and 64, resulting in mutual
15 counter-rotation thereof whereby optics 58 and 60 are
16 pushed farther away from each other. As explained by
17 Sarfarazi in U.S. patent 5,275,623, which is incorporated
18 herein by reference, increasing the distance between optics
19 58 and 60 will decrease the refractive power of the lens
20 doublet, thereby causing objects nearer the eye to form
21 focused images on the retina, so that when the ciliary
22 muscle contracts, the eye is accommodated for near vision.

23 The actual focal length of optic 14 which is to be
24 implanted within the lens capsule 16 is a function of the
25 size of the eyeball and refraction (myopia or hyperopia) of
26 the eye, among other things, and will vary from patient to
27 patient. An advantage of the present invention is that the
28 mechanism it provides for accommodative movement of optic
29 14 within capsule 16 causes the small radial motion of the
30 edge 19 of capsule wall to be amplified into a relatively
31 larger axial motion of the optic. This large accommodative
32 movement enables the eye to achieve a full range of
33 accommodation, from distant to near vision, and can
34 compensate for differences in the sizes of the eyeball and
35 refraction from patient to patient.

36 For some patients, however, it may be desirable to
37 provide for position adjustment within lens capsule 16, so
38 that optic 14 will be located at a suitable distance from

1 the center of the lens capsule, such that when the ciliary
2 muscle is completely relaxed, the eye is correctly focused
3 on infinity, this being the correct adjustment for far
4 vision. In practice, it is very difficult to position the
5 optic precisely during the implantation surgically without
6 a certain amount of trial and error, and therefore means
7 are preferably provided for allowing small adjustments to
8 be made to the axial displacement of optic 14. However, it
9 is possible to measure the refraction of the lens in situ
10 using, for example, a refractometer, and to correct the
11 refraction as outlined below.

12 This adjustment may be accomplished by means of two
13 alternative embodiments of the invention, which are
14 operable either separately or together, both of which are
15 shown schematically in Fig. 13. The first alternative
16 embodiment, which allows adjustment of optic 14 toward
17 posterior wall 18, makes use of a ring 70, which is formed
18 with a plurality of kinks 72. These kinks may be
19 straightened out during surgery so as to increase the
20 effective diameter of the ring 70 and produce an outwardly
21 directed radial force on linkage arms 74, whereupon there
22 results a net movement of optic 14 toward the posterior
23 wall.

24 Fig. 14 shows, pictorially, an adjustment tool 76 for
25 removing, either completely or partially, kinks 72 from
26 ring 70. Adjustment tool 76 is in the form of a pincer
27 having a pair of handles 78 and a pair of substantially
28 planar support members 80 opposite the handles and
29 rotatable about a hinge axis 82. Adjustment tool 76 is
30 inserted into the lens capsule so as to support kinks 72 on
31 respective ones of the support members 80. Adjustment tool
32 76 also includes a pair of flattening members shown
33 schematically as 84 which cooperate with support members 80
34 for pressing on ring 70 so that kinks 72 are flattened by
35 flattening members 84 bearing down on support members 80.

36 Referring again to Fig. 13, it will be seen that as a
37 second way of adjusting the lateral position of optic 14 in
38 the capsule, levers 74 are also provided with two kinks 75.

1 These kinks may be at least partially straightened using a
2 specially designed pincer, thereby effectively lengthening
3 the respective levers and causing a net axial movement of
4 the optic 14 in a posterior direction toward the focal
5 plane.

6 Referring now to Fig. 15, a specially designed pincer
7 for straightening out simultaneously both kinks 75 will be
8 described. A pincer shown generally as 86 includes a head
9 portion 88 having two upper aligned jaws 90 and two lower
10 aligned jaws 92. In use, the two kinks 75 in the levers 74
11 are respectively aligned between the two pairs of jaws such
12 that closing the jaws by means of a handle 94 flattens
13 kinks 75, and causes the desired axial movement of the
14 optic 14 in a posterior direction toward the focal plane.

15 As has been explained above, a resilient biasing force
16 may conveniently be provided by the natural elasticity of
17 the posterior capsule wall 18 and the edge of the lens
18 capsule 19. In this case, for those embodiments of the
19 invention which require the restoring force of the
20 posterior wall on the optic, the position of the optic 14
21 within the lens capsule 16 must be adjusted so that, for
22 correct far vision when the ciliary muscle is completely
23 relaxed, the rear surface of the optic 14 contacts the
24 posterior capsule wall 18. This too can be provided by the
25 methodology described with respect to Figs. 13-15.

26 In the preferred embodiments described hereinabove,
27 lens assembly 12 is mounted completely within lens capsule
28 16 and an inward radial resilient biasing force is provided
29 by the inherent elasticity of remaining portions of the
30 lens capsule. However, the lens capsule may be dispensed
31 with for some of these embodiments by providing auxiliary
32 springs which act as tensile elements 96, as shown in Figs.
33 5, so as restore the optic to its equilibrium position on
34 relaxation of the ciliary muscle, and by attaching or
35 anchoring the lever arms to the ciliary muscle or zonules.
36 The inward radial biasing force may comprise, for example,
37 a tensioned ring attached to the zonules or to the ciliary
38 muscle itself.

1 The present invention has been described, generally,
2 for lens implants utilizing rigid optics. Alternative
3 preferred embodiments of the above described embodiments of
4 the invention utilize soft optics which may have a number
5 of advantages over rigid optics. Firstly, the soft optics
6 may be folded during implantation, such that the opening in
7 the anterior wall of the lens capsule may be reduced.
8 Secondly, some of the joints, for example, those which
9 provide flexible joints at the juncture of the linkage arms
10 and the optic or between the fulcrum and the optic, may be
11 dispensed with and their function assumed by a slight
12 bending of the edges of the optic itself.

13 In general, the materials used in the present
14 invention are similar to those used in the prior art and
15 include nylon and proline for the resilient linkage arms
16 and the flexible elements, polymethylmethacrylate (PMMA) or
17 hydrogel for the rigid optic and silicone for the soft
18 optic. Preferably the rigid linkage arms and other rigid
19 elements are formed of stainless steel wire optionally
20 covered by proline or nylon or other inert material. The
21 surface of all or part of the lens system may be covered
22 with Haperin or other biologically active compound to
23 reduce body rejection of the lens system.

24 It is to be understood that, during cataract
25 operations, at least part of the anterior capsule wall is
26 usually destroyed and part of the posterior capsule wall
27 may also be damaged. Therefore, the term "posterior
28 capsule wall" as used in the specification and claims
29 embrace also partial capsule walls as appropriate.

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1 I CLAIM:

- 2 1. An intraocular lens assembly for implantation in a
3 human eye, said eye including a ciliary muscle and zonules
4 controlled by the ciliary muscle, the assembly comprising:
5 an optic having anterior and posterior surfaces
6 depending from a common edge;
7 at least two linkage arms, each being attached to the
8 optic at a first position on the arm thereof and
9 cooperating with ciliary muscle or the zonules at a second
10 position on the arm; and
11 at least two pivots, one of which is rotatably
12 attached to each respective linkage arm intermediate the
13 first and second positions.
14
- 15 2. An intraocular lens assembly for implantation in a
16 human eye, said eye including a ciliary muscle and zonules
17 controlled by the ciliary muscle, the assembly comprising:
18 an optic having anterior and posterior surfaces
19 depending from a common edge; and
20 at least substantially two rigid linkage arms, each
21 being attached to the optic at a first position on the arm
22 thereof and cooperating with ciliary muscle or the zonules
23 at a second position on the arm.
24
- 25 3. An intraocular lens assembly according to claim 2 and
26 further comprising:
27 at least two pivots, one of which is rotatably
28 attached to each respective linkage arm intermediate the
29 first and second positions.
30
- 31 4. An intraocular lens assembly according to Claim 1 or
32 claim 3, whereby changes in tension of the zonules cause
33 radial motion of the second position and rotation of said
34 linkage arms about their respective pivots.
35
- 36 5. An intraocular lens assembly according to any of claims
37 1, 3 or 4 wherein the assembly is adjusted so that when the
38 ciliary muscle is relaxed, the optic is located at a

1 predetermined distance from the rear surface of the eye for
2 correct far vision, and wherein contraction of the ciliary
3 muscle causes a radial motion of the edge of the lens
4 capsule, causing the linkage arms to rotate about said
5 pivots so as to axially displace the optic away from the
6 rear surface of the eye.

7

8 6. An intraocular lens assembly according to any of claims
9 1 or 3-5, wherein the linkage arms and pivots are so
10 arranged that said radial movement of second position of
11 the linkage arms causes the optic to move axially by a
12 distance substantially greater than the distance of said
13 radial movement.

14

15 7. An intraocular lens assembly according to any of
16 claims 1 or 3-6 and comprising a generally rigid ring
17 having a diameter greater than that of the optic and
18 wherein the lever arms and the rigid ring are attached at
19 said pivots.

20

21 8. An intraocular lens assembly according to claim 7
22 wherein the pivots comprise flexible portions in said
23 otherwise rigid ring.

24

25 9. An intraocular lens assembly according to claim 8,
26 wherein:

27 the ring is formed of at least two rigid sections
28 interconnected by a biologically inert sleeve so as to
29 allow twisting of respective portions of the sleeve
30 intermediate the rigid sections, and

31 said respective portions of the sleeve serve as
32 fulcrums.

33

34 10. An intraocular lens assembly according to claim 8 or
35 claim 9, wherein said ring is provided with one or more
36 initial kinks which can be at least partially straightened
37 during implantation of the lens assembly in order to adjust
38 the distance of the optic from the rear surface of the eye

1 to said predetermined distance.

2

3 11. An intraocular lens assembly according to any claims 1
4 or 3-10, wherein at least two optics are commonly coupled
5 to the respective linkage arms at the pivots.

6

7 12. An intraocular lens assembly according to any of the
8 preceding claims wherein the linkage arms are rigid,
9 intermediate said first and second positions thereof,
10 except at a flexible joint intermediate the first and
11 second positions.

12

13 13. An intraocular lens assembly according to any of
14 claims 1-11 wherein the linkage arms are rigid,
15 intermediate said first and second positions thereof,
16 except at at least one flexible joint intermediate the
17 first and second positions.

18

19 14. An intraocular lens assembly according to any of the
20 preceding claims, wherein a resilient bias operates on each
21 of said linkage arms to maintain the optic at the desired
22 distance from the rear surface of the eye, in response to
23 radial movement of said second position.

24

25 15. An intraocular lens assembly according to any of the
26 preceding claims wherein the eye also includes at least a
27 portion of a lens capsule including at least a peripheral
28 edge thereof attached to the zonules and wherein the
29 resilient bias is at least partially provided by the edge.

30

31 16. An intraocular lens assembly according to claim 15
32 wherein the lens capsule also includes at least a portion
33 of the posterior wall thereof and wherein the resilient
34 bias is at least partially provided by the posterior wall.

35

36 17. An intraocular lens assembly according to claim 16,
37 wherein the resilient bias is at least partially provided
38 by stretching of the posterior capsule wall attached to the

1 ciliary muscle at opposing extremities of the lens capsule,
2 and

3 the assembly is adjusted so that, when the ciliary
4 muscle is relaxed, the optic is located against the
5 posterior capsule wall.

6

7 18. An intraocular lens assembly according to claim 16 or
8 claim 17 and including and including an expanding ring
9 associated with the edge which contacts the edge portion of
10 the lens capsule and positions the posterior wall toward
11 the back of the eye and away from the center of the lens
12 capsule.

13

14 19. An intraocular lens assembly according to any of
15 claims 15-18 wherein a tensile member is attached to a
16 remaining portion of the lens capsule which is in turn
17 attached to the zonules.

18

19 20. An intraocular lens assembly according claim 14
20 wherein the resilient bias is at least partially provided
21 by a resilient tensile member attached to the zonules or
22 the ciliary muscle.

23

24 21. An intraocular lens assembly according to any of
25 claims 1-14 wherein the eye includes at least a portion of
26 a lens capsule including at least a peripheral edge thereof
27 attached to the zonules and wherein the linkage arms
28 cooperate with the edge of the lens capsule.

29

30 22. An intraocular lens assembly according to claim 21
31 wherein the portion of the lens capsule includes at least a
32 portion of the posterior wall and including an expanding
33 ring associated with the edge which contacts the edge
34 portion of the lens capsule and positions the posterior
35 wall toward the back of the eye and away from the center of
36 the lens capsule.

37

38 23. An intraocular lens according to any of the preceding

1 claims wherein the tension of the zonules causes the second
2 position of the linkage arms to move outward.

3

4 24. An intraocular lens assembly according to any of
5 claims 1-22 wherein the tension of the zonules causes the
6 second position of the linkage arms to move inward.

7

8 25. An intraocular lens assembly according to any of the
9 preceding claims, wherein at least one of the linkage arms
10 is attached to the zonules or the ciliary muscle at the
11 first position of the respective linkage arm.

12

13 26. An intraocular lens assembly according to any of the
14 preceding claims and including a pivot at the attachment of
15 the respective linkage arms to the optics.

16

17 27. An intraocular lens assembly according to any of the
18 preceding claims, wherein the respective linkage arms are
19 attached to the edge of the optic.

20

21 28. An intraocular lens assembly according to claim 27
22 wherein the attachment at the edge of the lens comprises
23 attachment of the linkage arms along the edge of the optic
24 by a flexible coupling which allows for rotation of the
25 linkage arm with respect to the edge of the optic.

26

27 29. An intraocular lens assembly according to any of
28 claims 1-26 wherein the respective linkage arms are
29 attached to a face of optic.

30

31 30. An intraocular lens assembly according to any of the
32 preceding claims, wherein at least a portion of the linkage
33 arms are provided with one or more initial kinks which can
34 be at least partially straightened during implantation of
35 the lens assembly in order to adjust the distance of the
36 optic from the rear surface of the eye to said
37 predetermined distance.

38

1 31. An intraocular lens assembly for implantation in a
2 human eye, said eye including a ciliary muscle and zonules
3 controlled by the ciliary muscle and at least a portion of
4 a lens capsule including an edge thereof and at least a
5 portion of a posterior wall thereof, the assembly
6 comprising:

7 an expanding ring associated with the edge which
8 contacts the edge portion of the lens capsule and positions
9 the posterior wall toward the back of the eye from center
10 of the lens capsule; and

11 an optic associated with the expanding ring.
12

13 32. An intraocular lens assembly according to any of
14 claims 18, 22 or 31 wherein the edge portion also bears
15 against the posterior wall to further position the wall
16 toward the back of the eye.
17

18 33. An intraocular lens assembly according to any of
19 claims 18, 22, 31 or 32 wherein the expanding ring also
20 provides a resilient radial force on the edge.
21

22 34. An intraocular lens assembly for implantation in a
23 human eye, said eye including a ciliary muscle and zonules
24 controlled by the ciliary muscle and at least a portion of
25 a lens capsule including an edge thereof, the assembly
26 comprising:

27 an expanding ring associated with the edge portion of
28 the lens capsule and which provides a resilient radial
29 force on the edge; and

30 an optic associated with the expanding ring.
31

32 35. An intraocular lens assembly according to claim 33 or
33 claim 34 wherein the expanding ring bears against the edge
34 and provides an outwardly directed radial force on the
35 edge.
36

37 36. An intraocular lens assembly according to claim 33 or
38 claim 34 wherein the expanding ring is attached to the edge

1 and provides an inwardly directed radial force on the edge.

2

3 37. An intraocular lens assembly according to any of
4 claims 18, 22 or 31-36 wherein the ring is formed of
5 alternating rigid and elastic portions.

6

7 38. An intraocular lens assembly for implantation in a
8 human eye, said eye including a ciliary muscle and zonules
9 controlled by the ciliary muscle and at least a portion of
10 a lens capsule including an edge thereof and at least a
11 portion of a posterior wall thereof, the assembly
12 comprising:

13 an expanding ring associated with the edge comprising
14 alternating rigid and elastic portions; and

15 an optic associated with the expanding ring.

16

17 39. An intraocular lens assembly according to claim 38
18 wherein the expanding ring is attached to the edge of the
19 lens capsule.

20

21 40. An intraocular lens assembly according to claim 38
22 wherein the expanding ring bears against the edge of the
23 lens capsule.

24

25 41. An intraocular lens assembly

26 30. For use with the intraocular lens assembly according to
27 claim 10 or claim 29, an adjustment tool for removing said
28 kinks, the adjustment tool comprising:

29 a pincer having a pair of handles and two pairs of
30 aligned jaws opposite said handles rotatable about a hinge
31 axis, for insertion into the ciliary body and supporting
32 thereon respective ones of said kinks, such that closing
33 the handle presses the kinks between respective pairs of
34 said jaws thereby flattening the kinks.

35

36 42. For use with the intraocular lens assembly according to
37 claim 10 or claim 29, an adjustment tool for removing said
38 kinks, the adjustment tool comprising:

1 a pincer having a pair of handles and a pair of
2 substantially planar support members opposite said handles
3 rotatable about a hinge axis, for insertion into the
4 ciliary body and supporting thereon respective ones of said
5 kinks, and

6 a pair of flattening members cooperating with the
7 support members for pressing the kinks towards the support
8 members and thereby flattening the kinks.

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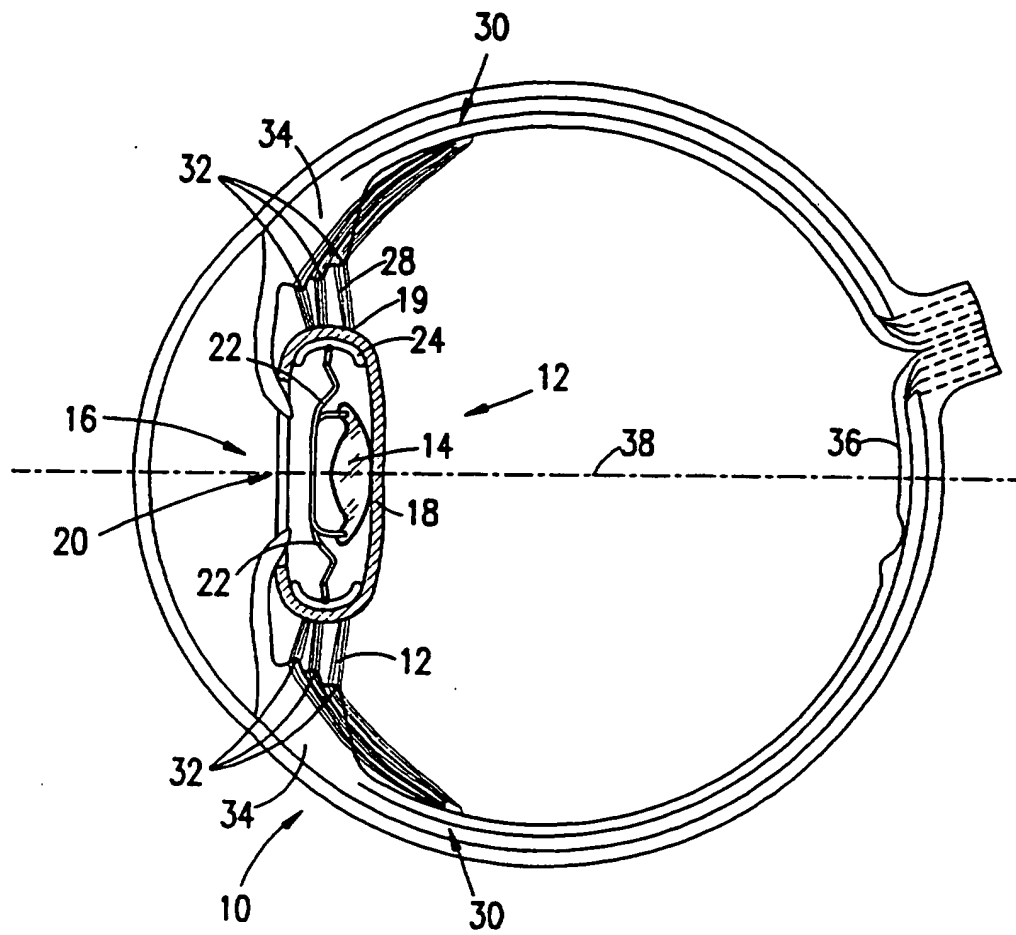
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FIG. 1

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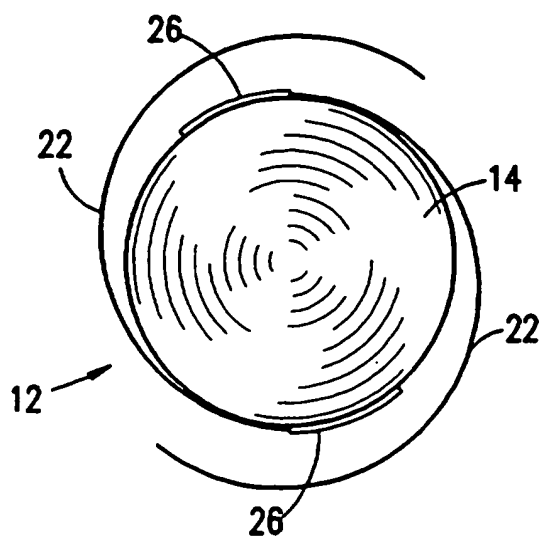


FIG. 2A

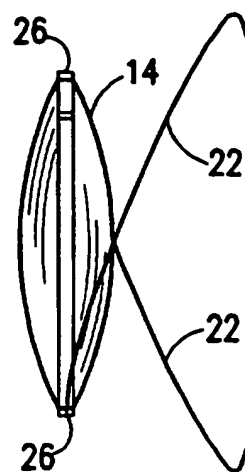


FIG. 2B

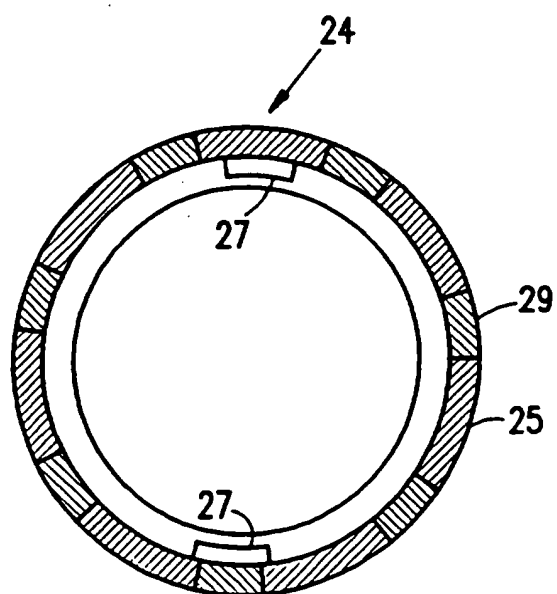


FIG. 3

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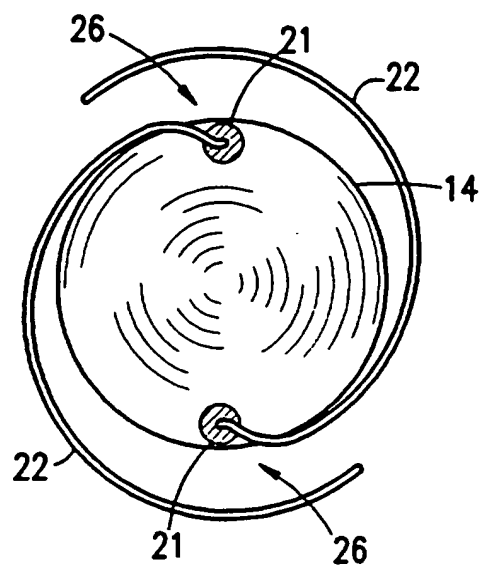


FIG. 4A

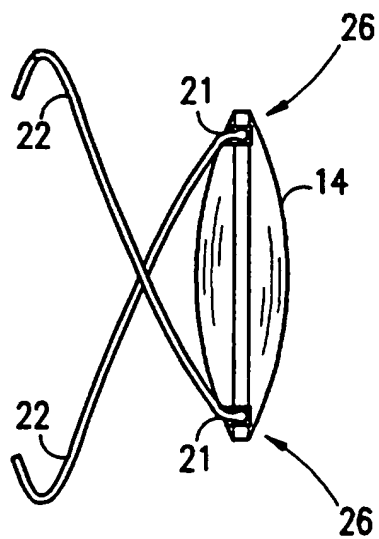


FIG. 4B

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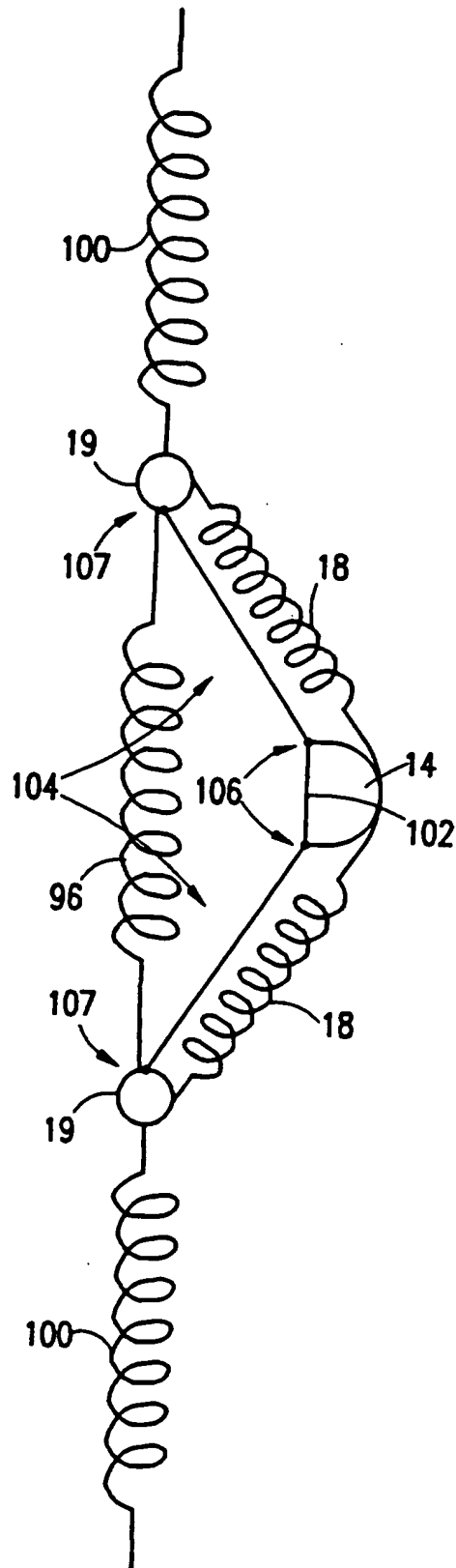


FIG. 5

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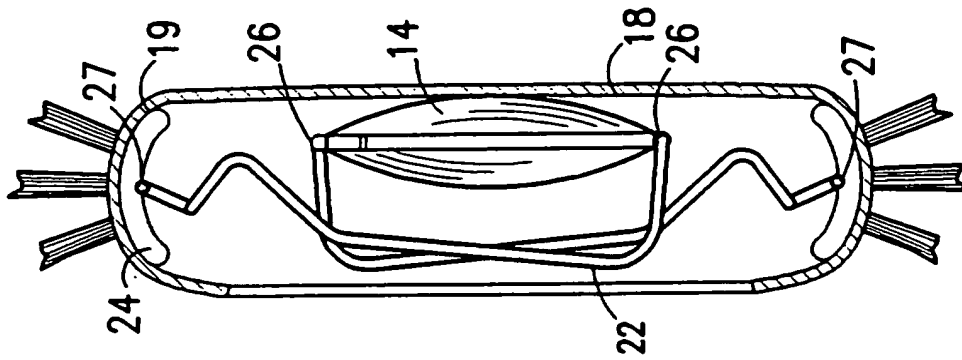


FIG. 6B

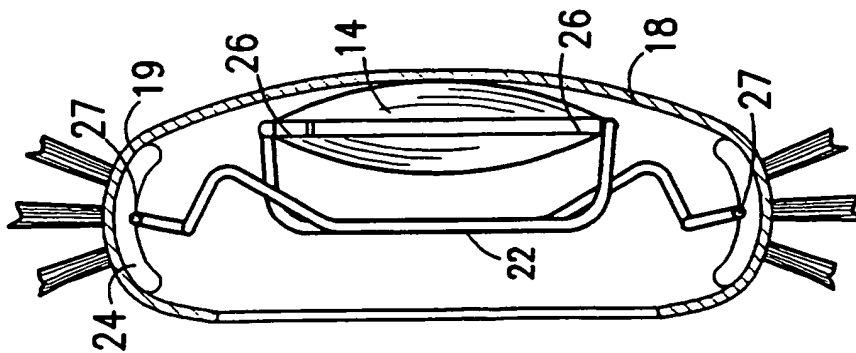


FIG. 6A

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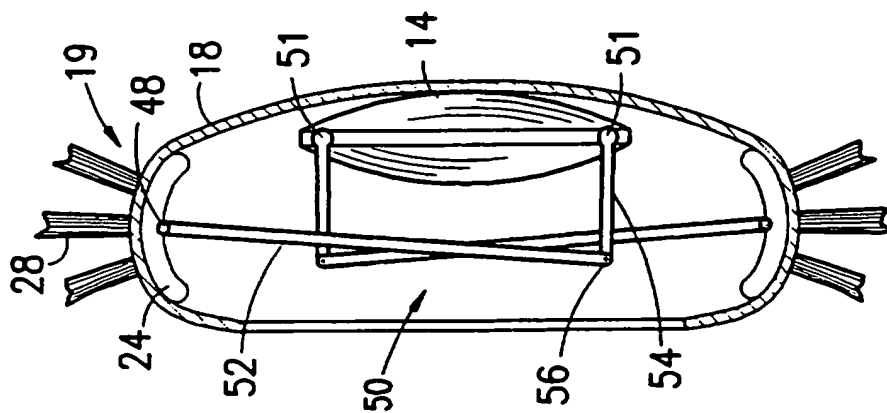


FIG. 7A

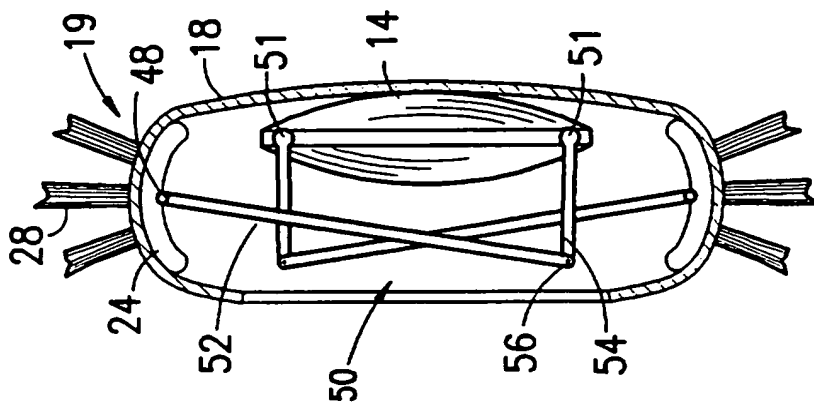


FIG. 7B

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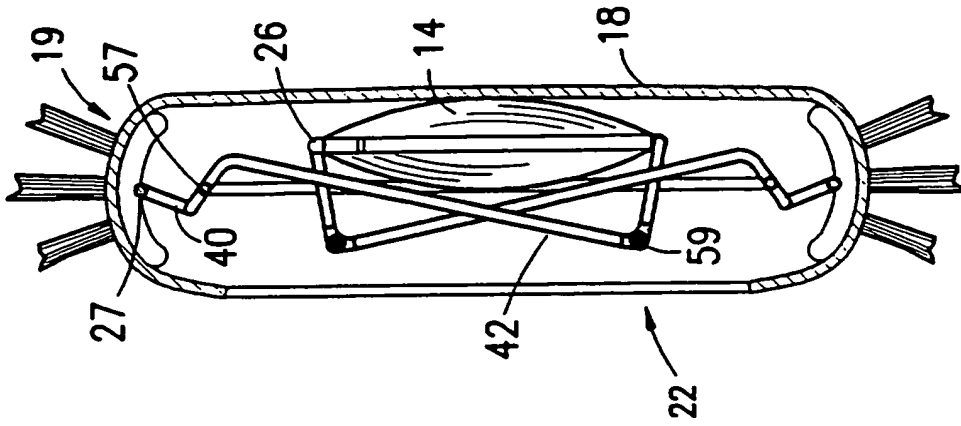


FIG. 8B

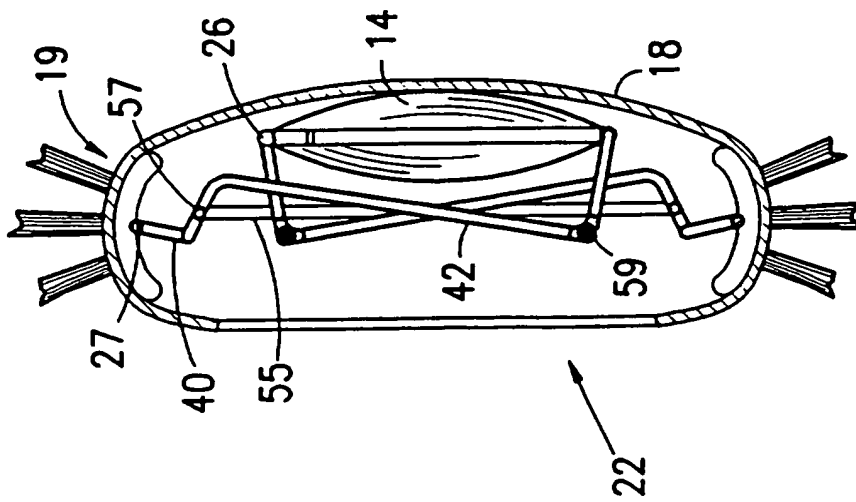


FIG. 8A

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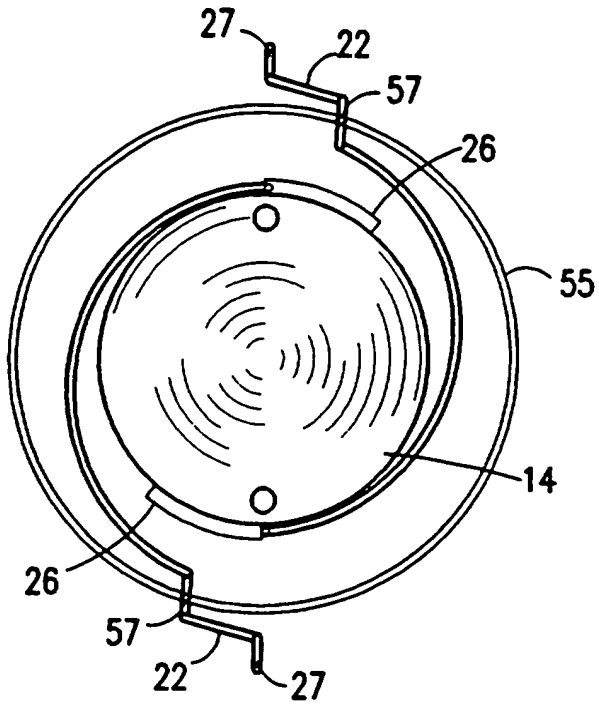


FIG. 9

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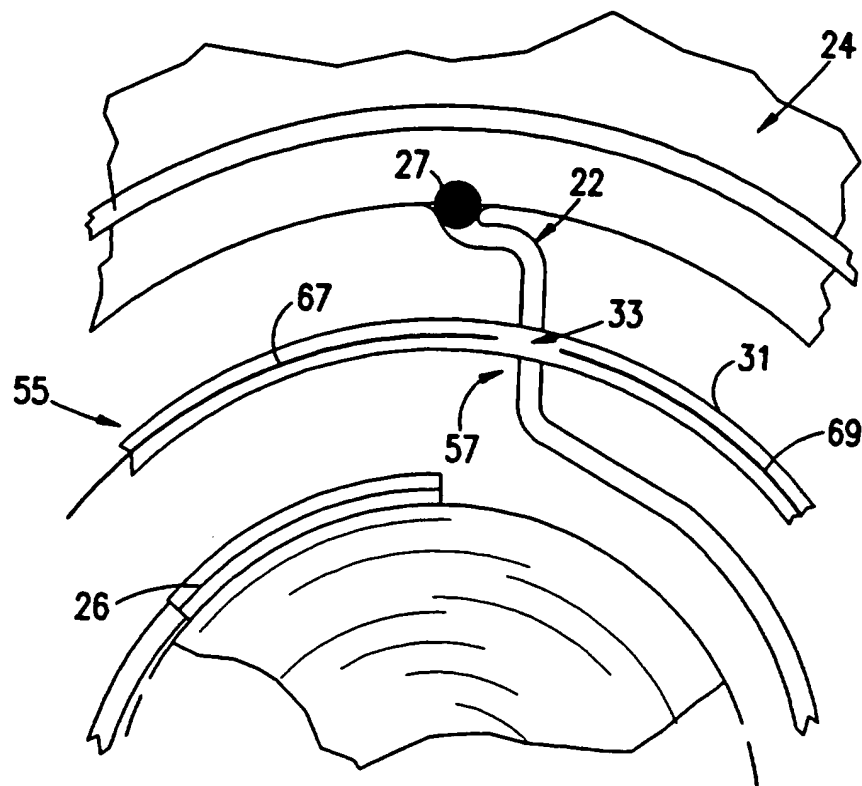


FIG. 10

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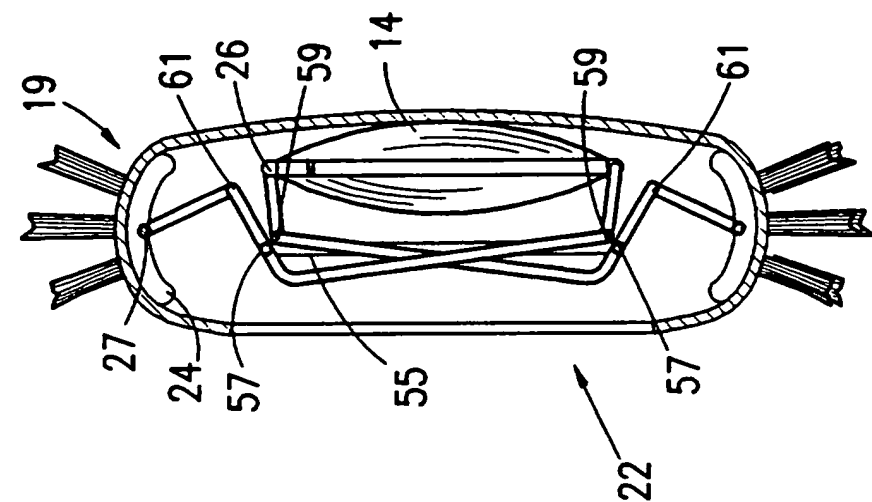


FIG. 11B

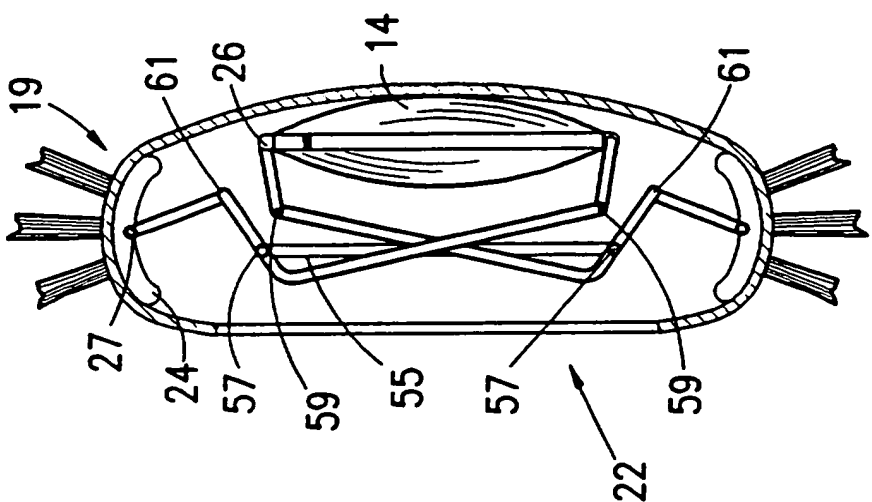


FIG. 11A

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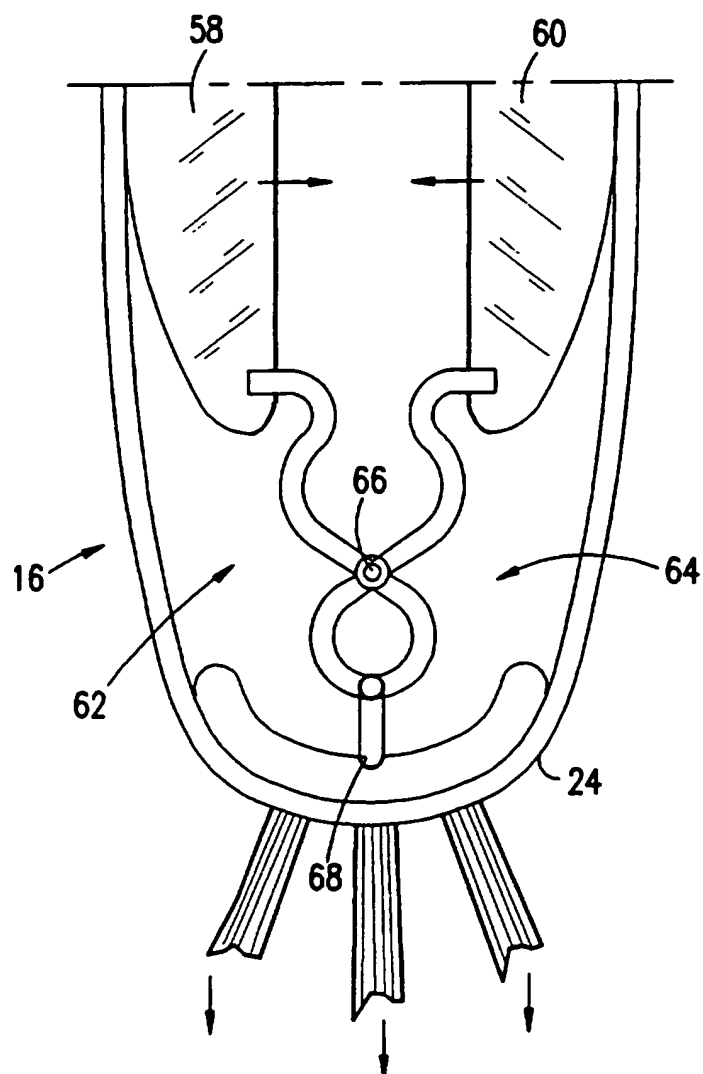


FIG. 12

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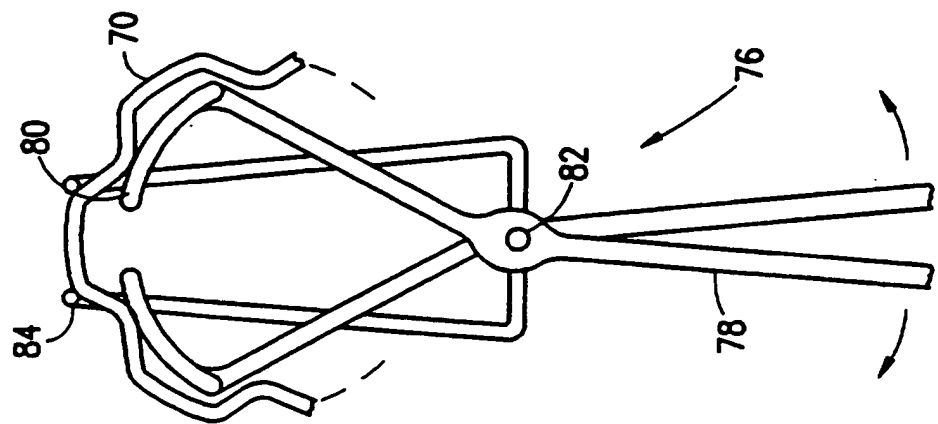


FIG. 14

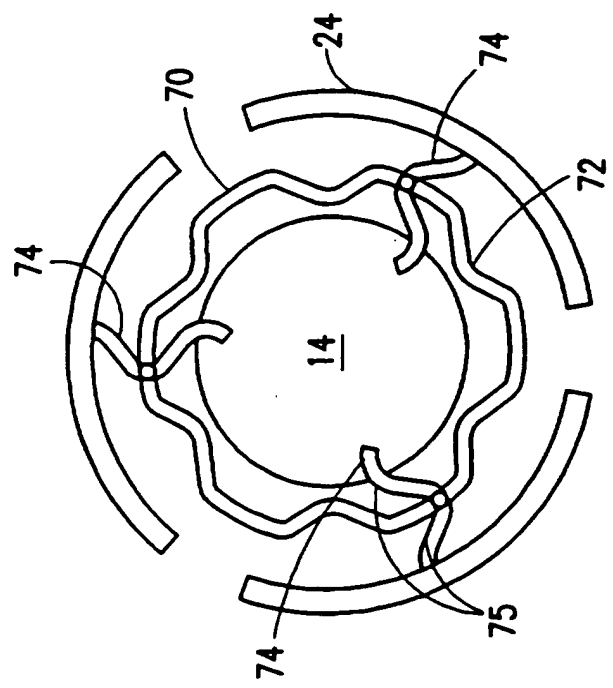


FIG. 13

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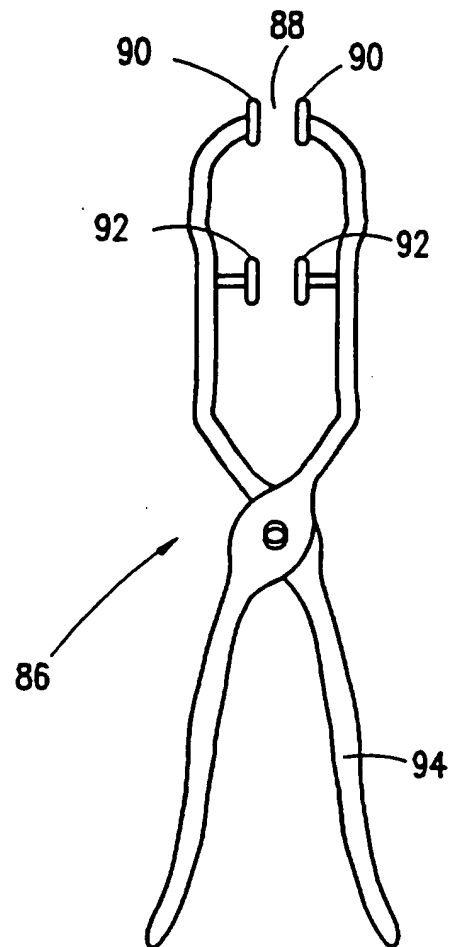


FIG. 15

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